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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Using the TRACK-TBI (*Transforming Research and Clinical Knowledge in TBI)* dataset we have created an Information Commons that integrates clinical, imaging, proteomic, genomic, and outcome biomarkers based upon the domains of the TBI Common Data Elements. The comprehensive TBI-CDE outcome measures allow for analyses of biomarker associations with a variety of measures. Available prognostic models have been evaluated against new prognostic models for TBI and found to be unsatisfactory using a multivariate approach that goes beyond the crude definitions of Mild, Moderate and Severe TBI. The latest neuroimaging methods including Quantitative CT, DTI, and resting-state functional MRI are surpassing other methods for predicting TBI patient outcomes. In emergency settings where high resolution neuroimaging is not available, rapid measurement of proteomic markers is appearing to be a valuable adjunct to current screening practices for ruling out TBI. Most importantly improving the collection of biomarkers in TBI patients will be vital to the design of future clinical trials. For future plans during Year 2 we are on target to complete the original tasks to conduct multivariate diagnostic and prognostic modeling across all aims and CDE domains.

15. SUBJECT TERMS
Traumatic Brain Injury; Common Data Elements; Prognosis; Outcomes

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V¦æ̃{ æ̃æ̃&ÁÓ¦æ̃¡ÁQ¦b̆¡ˆ̂ÁÇÝÓᶜⱭ̂Á^{ æ̃¦•Á¦̂}^Á¦~Áˆ̃@̆Á̂¦^æ̃^•̂Á̂}^̆Á^̃̂Á^^å•Áå̃Á̆¡ãã̃æ̃ˆ̂Áæ̃¦å̃&æ̃ãã̃æ̃¦Á {̂^åå&æ̃¦^ÊVᴸ@̆Áç̆¦æ̃¦Á[æ̃¦Áˆ~@̆Áč̆å̂Áæ̆ÁǶç¢ᶜ̂}•ã̃¡ˆ̂æ̃¦æ̃¦: ^Á̂~@̆Á*existing* åæ̃æ̃Á^åᶜÁ¦[{ Á̂~@̆Á {̆¡æ̃&X̆}ᶜ̂¦Á̆¡̃Á̂ᶜ̆å̂Á̂~@̆Á̃ã̃̂^åÁǓ̈ÔŜ̈ÝÓᶜ̂Á̂*Transforming Research and Clinical Knowledge in TBI.*ÁǓ̈ÔŜ̈ÝÓᶜ̂^¦¦^̂^¦•̂Á̂~@̆Á̂æ̃̆*^̂•̂Á̆ˇ|ã̃¡æ̃æ̃ã̃æ̃^ÁÝÓᶜ̂åæ̃æ̃æ̃æ̃æ̃^Áæ̃&̆¦¦•̂•̂Á̂~@̆Á̆¡̃b̆¡ˆ̂Á •]^̂&č̆¡{ Á̂¦[{ Á̆&¦[}&̆̆̂••ã̃̂}Á̂¦&¦{ æ̃æ̃ã̃@̆̂ÝÐᴸⱤŬⱭ̆æ̃ã̃*Ê̆æ̃¦¦[[åå̃ã̃¡•̂]^̂&ã̃¡^}̆•̂æ̃¡å̆ˇč&¦{ ^Á æ̃•^̂••{ ^}ᶜ̂•̂ÊV̆~@̆ÁÓ̈Ũ̆ÖÁÝÓᶜ̂Á¦¦b̆&̃Á̂Á̆å^¦̂æ̃¦̆ã̃*Á̂¦[^^̂ᶜ̂¢ᶜ̂^}•ã̃¡̆^̂æ̃¦^•̂•̆æ̃¡~Áᶜ̂@̃ã̃Á @̃̆@¦Á̆¡æ̃ˇ¦æ̃¦&Á̆@¦[¡̂Á~ÁÝÓᶜ̂ˇ̆åb̆&¦ÊVᴸ@̃ã̃Á̂¦[¦\Áã̃̆æ̃¡̆[Áæ̃̆æ̃çæ̃¦&ã̃̆*Á̆¦ˇ¦Á̂åå̃ã̃*Á̂¦~Á ÝÓᶜ̂æ̃¦å̃̆Á̆]¦[çã̃̆*Á̂¦[*̂̂][æ̃&Á^̂¢ᶜ̂]å•̂å̃æ̃̆̂}̃æ̃̆å̃ã̃ã̃̆æ̃¦•̂æ̃æ̃̂ã̃\Á̂¦[¦Á̂^̆¦̃ã̃ᶜ̂^̂}&̆[*̂}ã̃̆ᶜ̂^Á æ̃¦å̃¦•̂&@̆[¦[*̂̆&̆æ̃ã̆@̆̆æ̃æ̃̆̂ã̃Á̂¦[å^¦̆¦̃Á^¦¦¸ã̃*ÁÝÓᶜ̂Êᴸ̆@̃ã̃Á̂̆^̂æ̃¡ã̃*Á̆¦&̆@̆ç̆¡å̆å̂^Á̂¦[{ Á¦¦¸ã̃*Á æ̃æ̃¦•̂Ḱ

Œæ̃¦̂Ḱ̂VᴸÁå̆̂^̂ç̂¦[}̆Á̂]]̆¡̆ç̂^å̆Á̂¦[*̂̂}•̂æ̃Ê̆̂æ̃ã̃̆̂}•̂æ̃&̆æ̃¦å̂ˇ¦&̆{ ^Á̂[å•¦̂Á̂¦[¦ÁÝÓᶜ̂ÊᴸÁ Œæ̃¦̂ḾGḰVᴸå̆æ̃^̂}̆ã̃æ̃Á̆ˇ̂¦[æ̃¡̆æ̃ã̃*Á̂¦æ̃ã̃¦{ æ̃^\̆̂•̂•̂Á¦¦¸æ̃ã̃æ̃}•̂æ̃̆ã̃ã̃æ̃å̂ˇ¦[*̂̂}•ã̃¡̆&̆ÁÝÓᶜ̂ÊᴸÁ Œæ̃¦̂ḾHḰVᴸå̆æ̃^̂}̆ã̃æ̃Á̂¦[^̂¦[{ æ̃&̆æ̃¦å̂Á̂^̂}̆¦{ æ̃¦æ̃•̂&ã̃̆æ̃æ̃̆}•̂Á̆ã̃@̆ÝÓᶜ̂¦̆@̆}̆[̆ĉ}•̂ÊᴸÁ

2. KEYWORDS

V¦æ̃{ æ̃æ̃&ÁÓ¦æ̃¡ÁQ¦b̆¡ˆ̂LᴸÔ̂[{ { []}ÁÖæ̃æ̃æ̃æ̃Á̂Ô|^{ ^}̂•̂LᴸÚ¦[*̂̂}•ã̃¡LᴸÁˇ&̆[{ ^•̂Á

3. OVERALL PROJECT SUMMARY

Aim 1. To develop improved prognostic, diagnostic and outcome models for TBI.
Task 1: Cleaning baseline data.

Ú¦[*̂̂}•̂••̆Ḱ̂Ó̂æ̃̆^̂¡ã̃̆̂¦̆̂å̂æ̃æ̃̆̂Ó̆æ̃̆Á̂^^^}&̂¦̆̂æ̃̆}̆^Á̂å̆æ̃̆Á̂¦̆æ̃æ̃̆{ æ̃æ̃̆å̃̆&̆}•ã̃ᶜ̂}&æ̃æ̃•̂&̆¦¦̆^̂čᶜ̂åᶜ̂Á} Á •&̂@̆å̂¦^ÊVᴸ@̃ã̃Á̂¦[*̂̂}•̂•̂Á̂æ̃æ̃^Á̂}̆æ̃æ̃̆|̂å̆•̂Á̂¦̂[ç̂̆¦[*̂Á̆ã̃̆å̃@̆Á̂¦ᶜ̂¦̆æ̃æ̃̆\̆Á̆ã̃æ̃̆¦̃ã̃¦Áᶜ̂æ̃̆̆ḾFᴸÊᴸÁ

<mark>Vᴸ@̃ã̃̂å̆^æ̃æ̃¡̆̂Á̂~@̆Á̂åæ̃æ̃̆&̆^¦æ̃̆æ̃ã̃̆*Á̂¦~•̆ˇ̂[ᶜ̂æ̃̆^Á̂¦[çã̃¡—å̆ã̃̆å̆æ̃̆̂Ḱ̂̆Hᴸ̂Áæ̃^̆¦^Á̂¦[̂[̆}̂ã̃¡̆å̂^^**TRACK-TBI Summary Statistics for Data Curation" (Appendix A).** Vᴸæ̃̆Á̂^̂¦[¦̂æ̃̆̂¦[¦̂^ç̂•̂Ǣ̂æ̃̆̆Á ¦~~¦^¦^}&̆Á̂ˇ̆ã̃̆^Á̂¦[Á̆&¦¦¦}̆æ̃̆̆å̆ˇč̆̂¦̂ã̃̆ç̂•ã̃̆æ̃̆æ̃̆¦•̂&̆¦[¦å̆&ã̃̆*̂æ̃̆æ̃¦̂•̂æ̃̆^̂Á̂ã̃̆*̂~@̆ÁǓ̈ÔŜ̈ VÓᶜ̂Áᶜ̂¦[̆Óᶜ̂æ̃æ̃̆æ̃^̂åᴸEᴸᴸÝ̂^æ̃æ̃[Á̂¦|æ̃¦̂Á̂¦Á̆ˇ{ ã̃̆̆̆æ̃ã̃̆Á̆ˇ̃ã̃̆^Á̆¦ᶜ̂Áᶜ̂Q̈ᴸÝÓᶜ̂Q̃ᴸÊᴸ</mark>

Task 2: Prognostic modeling.
*Subtask 1:*ᴸ̂Xæ̃æ̃̆ã̃̆æ̃æ̃̆}̆̆Á̆~Á̆ç̂ã̃̆¦ã̃̆*̂̆Á̂¦̂¦[å̆&̆¦ã̃̆}̆̆Á̂¦[å̂^•̂Á̂¦̂}̆^Á̆ã̃@̆ÁǓ̈ÔŜ̈ÁÝÓᶜ̂Á̆æ̃æ̃æ̃^̂}̆—å̂ᴸÁ

Ú¦[*̂̂}•̂•̂ḰᴸV̂¦[̂Á̂ç̂ã̃̆¦ã̃̆*̂̆Á̂¦[å̂^•̂Á̂¦¦̂Á¦̆^åæ̃̆&ã̃̆*̂̆Á̆ˇ̂&̆¦{ ^•̂æ̃̆¦Á̆ã̃å̂ÁÝÓᶜ̂Q̂Á̆^̂¢ᶜ̂æ̃̆ã̃̆æ̃̆æ̃^̂åᶜ̂Á̆ã̃@̆̆æ̃̆Á Ǔ̈ÔŜ̈ÝÓᶜ̂̆̆å̆æ̃̆̆ˇ̆}̆̂å̂̆Á̂^̂~̂¦[̂¦̂Á̆•̂æ̃æ̃̆~̆æ̃&̆̃¡̃æ̃̆̂ĹŜ̂æ̃̆•̂{ æ̃æ̃^̂å̂æ̃ᴸÊᴸGᴸÊᴸFᴸᴸDᴸ̂Êᴸ^]¦̂ã̃¡̆[¦̂~@̆Á<mark>
]ˇ̆à̃|ã̃̆@̆̆å̂¦¦̂æ̃̆̆ˇ̆—&̆ã̃̆[̂å̆̆Á̂¦[çã̃¡̆[¦̂å̂å̂Áᶜ̂Q̂ᴸ]^̂}̆å̂ã̃̆ç̂ᴸÊᴸ</mark>

<mark>Œᶜ̂&@̆ˇ̆*̂̆Á̂~@̆̆̆Á̂æ̃æ̃¡̆¡ã̃̆̆^̂Á~¦̂æ̃æ̃̂}̆̂̆̆̆̃æ̃̆̂}̆•̆Á̆ã̃̆@̆̆Á̂åæ̃æ̃̆Á̂åæ̃æ̃^̂Áᶜ̂æ̃æ̃̆&̆¦æ̃̆|̂æ̃̆æ̃̆}̆̆ã̃̆¦b̆¡ˆ̂ÝÓᶜ̂Á^̂¦[ç̂¦|̂&̆¦{][^̂ᶜ̂¦̂ã̃̆Ê̆æ̃ᴸÁ •¦[^̂^̂Á̆ã̃̆åᴸ̂Áᴸ̃—̂^̂¦ᴸᴸ̂¦[̂Áåã̃̆æ̃à̃æ̃̆|ã̃̆*̆̆æ̃æ̃{ ^}•̂æ̃̆æ̃^̆ᴸᴸ̂¦[[^Á̂ç̂æ̃æ̃̆æ̃̆æ̃̆æ̃^̂å̆Á̂¦Á̂ç̂ã̃̆¦ã̃̆*̂̆Á̂¦[*̂̂}•̂&̆Á {̂[å̂^•̂Á̂¦¦̂ÁÝÓᶜ̂æ̃̆̆å̂Á̂ç̂¦][^̂å̂æ̃¦̂Á̂^̂åæ̃̆̆^̆Á̂¦[[̂Á̆ˇ̆&̆{ ^̂æ̃̆ĉ̂¦̂ÁÝÓᶜ̂Á^̂^̂}̂~̂&̆&̆å̂Áæ̃̆æ̃æ̃{ }̆•̂Á ¸̆ã̃@̆̆ÝÓᶜ̂¦[{ Á̂~ÁǓ̈ÔŜ̈ÝÓᶜ̂ᴸ̂¦[̂åᴸ̆æ̃¦ᴸÁᴸ̂^̂¦¦^̂čᶜ̂Á̂à̃̆^̂ç̂æ̃æ̃̆}̆æ̃æ̃&̆̂@̆̂¦¦̂̆ᴸÝÓᶜ̂Á̂æ̃æ̃¡̂Á̆^̂}̆{ Á ᶜ̂@̆^^̆&̆̂}̆ĉ̂¦̆æ̃̆̆@̆̆ÁᴸẼã̃æ̃̆å̂ÁŨæ̃æ̃¦•̂ᴸ̂Á̂^̂ç̂æ̃æ̃æ̃̆æ̃̆å̂ç̂̆Á̂|̂¦[*̂̂}•̂&̆Á̂¦[å̂^¦̂Á̂¦[å̆Á̆Ô|̂æ̃̆*̂[¸̆̆Á Ŭˇ̆&̆[{ ^̂Ê̆&̆^¦̂¦̂Áç̂¢ᶜ̂}̆å̆¦̆ÁÔŬ̂ÙᴸÖ̂D̆æ̃æ̃̆Á̂¦[}̆̆æ̃æ̃æ̃^̂|̂æ̃¡̂å̆^LᴸᴸU}̆̂¦̆Á̂¦[å̆|̂å̆Áæ̃æ̃̆æ̃æ̃^̂å̂}̆̆̂@̆̆Á Ô̈Ů̈Ŭ̂Ṕ̂æ̃čᶜ̂å̆å̂æ̃̆æ̃̆å̆æ̃̆æ̃̆å̆æ̃̆æ̃̆[çᴸᶜ̂@̆¡ã̃̆Á̂¦[Ṕ̂æ̃̆¡ᴸ̂^̂~̂^̂ᴸÊᴸVᴸ@̆Á̂Ṕ̂^̂ç̂@̆¡|̂æ̃̆å̂•̆ᴸᴸ̂¦[••ã̃̆¡̆å̂¡̂̆̆^̂^åå&æ̃̆•̂æ̃^̆̆~HᴸᴸẼᴸ æ̃̆æ̃æ̃^Ḙ̆[}̆̆@̆̆ÁŨ̈Ů̈Ŭ̂Öᴸᴸ̂^̂^Áæ̃̆æ̃̆̂¦̂: æ̃å̂Á̆ã̃@̆}̆æ̃̆æ̃æ̃̆æ̃̆^Áæ̃̆å̆Á̆ˇ̆|ā̃̆æ̃̆æ̃æ̃æ̃̆̂^̂Á̂¦[[̂¦ã̃̆̂}̆æ̃æ̃̆̆æ̃̆å•̂Á ¦^̂*̂̂•̂•ã̃̆^̂Á̂¦[å̂•̂ᴸÊᴸ</mark>

<mark>Ŭ~Á̂~@̆ÁHᴸÎ̂ᴸᴸ̆~Áᴸ̂Ì̂ Í̂ᴸ̆æ̃æ̃æ̃^̂}̆̆æ̃̆&̆ˇ̆å̂¦̆å̆æ̃̆æ̃@̆̆̂æ̃čᶜ̂å̂Áᶜ̂^̂å̆æ̃̆Áæ̃æ̃̂^̆Ẽ̂Î̂ᴸÁ̂^̂æ̃æ̃•̂Lᴸᴸᶜ̂̂^̆¦ᴸᴸ̂ˇ̆æ̃̆æ̃̆*̂̂æ̃̆æ̃̆*̂Ê̂Á GḰ.̂Í̂Ì̂Dᴸ̃ᴸᴸÍ̂̆Ẽᴸᴸ̂ç̂̆ᴸᴸ̂MᴸĜJ̈€ᴸ̂D̆̆Á̂¦^̂•̂•̂̂}̆čᶜ̂å̆Á̆ã̃̆@̆æ̃̆Ö̂|̂æ̃æ̃*̂[̆̆̂ᴸ̂Ô̂[{ æ̃æ̃Ů̂&̆¦^̂å̆Áᶜ̂ÔŬ̈Ů̂D̆̃Ạ̈FᴸÌ̂̆ẼᴸQ̂̆ã̃̆̆Áᴸ̂ÝÓᶜ̂Á]][ˇ̆|̂æ̃æ̃̆|̂̆}̆Ẽᴸ̂¦[̆@̆æ̃̆¦ᴸᶜ̂ã̃̆ˇ̆•̂|ˆ̂å̂æ̃^̂|[̂}̆å̆Á̂¦[å̂^•̂ᴸ̂æ̃̆å̆æ̃̆̆^̂̆[¦̂æ̃æ̃̆̂̃—¦{ æ̃̆&̆ÁÇ̂ã̃̆ˇ̆}̃^ÁFᴸDᴸ̆ã̃̆@̆̆æ̃æ̃^̆̂æ̃æ̃̆æ̃^̆̆</mark>

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The calibration plot shows:

Intercept	-0.299
Slope	0.261
C (ROC)	0.562

Y-axis: Observed 6 month unfavorable outcome in TRACK-TBI

X-axis: Probability of 6 month unfavorable outcome

Legend:
- Ideal
- Nonparametric
- △ Grouped patients

Unfavorable

Favorable

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Figure 1. Calibration plot of Nijmegen Jacobs combined model in 386 patients with GCS 14-15.

Figure 2. Calibration plot CRASH computed tomography model. [illegible highlighted text]

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Intercept   −1.064
Slope   1.441
C (ROC)   0.913

Observed 6 month unfavorable outcome in TRACK-TBI

- - - Ideal
······· Nonparametric
△ Grouped patients

Unfavorable

Favorable

Probability of 6 month unfavorable outcome
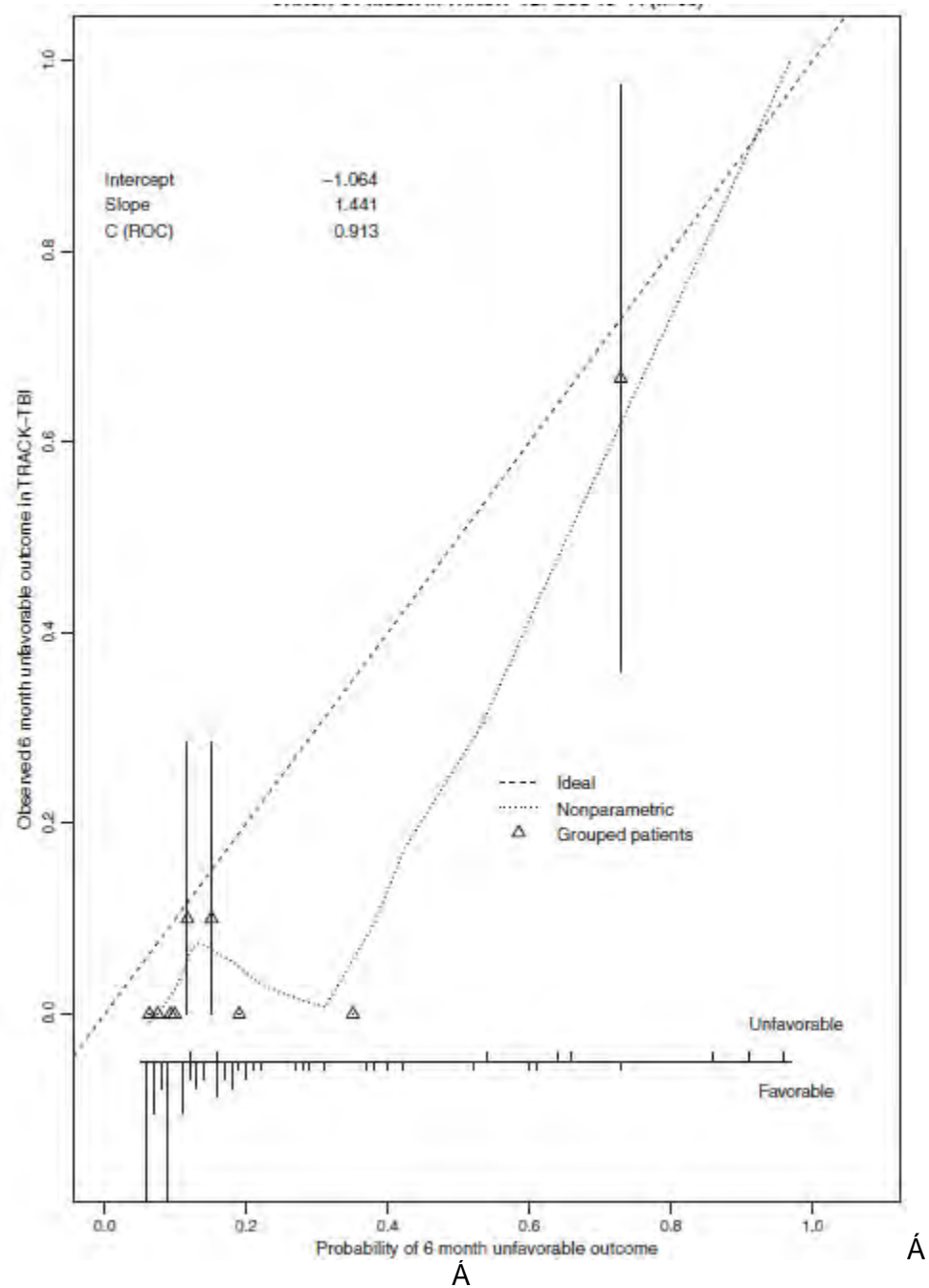
Figure 3. Calibration plot CRASH computed tomography model (original population).

Table 1. **Baseline characteristics for 386 patients with 3 and 6 month follow-ups.**

Characteristic	Missing	No. (%)
Age (median, IQR)	0	44 (27–58)
Male gender	0	271 (70)
Cause	4	
Road traffic accident		179 (47)
Fall		133 (35)
Assault		54 (14)
Struck by/struck against person or object		14 (6)
Other		2 (1)
GCS	0	
15		290 (75)
14		81 (21)
13		15 (4)
Pupil reactivity	61	
Both reactive		319 (98)
One reactive		5 (2)
None reactive		1 (0)
Psychiatric medical history	0	118 (31)
Hypoxia	2	23 (6)
Hypotension	1	13 (3)
Previous TBI (with and without hospital admission)	11	198 (53)
Education	12	
Low		37 (10)
Middle		202 (54)
High		135 (36)
Alcohol intoxication	228	52 (33)
ISS (median, IQR)	152	16 (10–18)
AIS head	152	
0		34 (15)
1		6 (3)
2		27 (12)
3		70 (30)
4		83 (35)
5		14 (6)
Extracranial injury	152	53 (23)
Marshall CT	0	
1		232 (60)
2		134 (35)
3		9 (2)
4		4 (1)
5		5 (1)
6		2 (1)
Facial fracture	0	53 (14)
EDH	0	12 (3)
tSAH	1	103 (27)
Mid-line shift	1	10 (3)
Third ventricle obliteration	2	11 (3)
Contusions	1	61 (16)
Petechial hemorrhage	1	3 (1)

GCS, Glasgow Coma Scale; TBI, traumatic brain injury; ISS, Injury Severity Score; AIS, Abbreviated Injury Score;

Table 2. Univariate Predictors of 3 and 6 month GOSE-E (n=386).

Predictors	Common OR (95% CI) (3 months)	p value	Common OR (95% CI) (6 months)	p value
Age (per 10 years)	1.2 (1.1–1.3)	<0.001	1.2 (1.1–1.3)	0.002
Male gender	0.9 (0.6–1.4)	0.678	0.8 (0.6–1.2)	0.316
Cause		0.021		<0.001
MV	Ref		Ref	
Fall	1.4 (0.9–2.1)		1.6 (1.1–2.4)	
Assault	2.2 (1.3–3.6)		2.6 (1.5–4.5)	
Struck by/strike against	1.3 (0.5–3.4)		0.6 (0.2–1.7)	
GCS		0.299		0.015
13	Ref		Ref	
14	0.6 (0.3–1.6)		0.3 (0.1–1.0)	
15	0.5 (0.2–1.3)		0.3 (0.3–0.7)	
No or one pupil reactive	2.4 (0.6–9.6)	0.205	3.8 (1.1–13.5)	0.039
Psychiatric medical history	2.2 (1.5–3.3)	<0.001	2.9 (1.9–4.2)	<0.001
Hypoxia	2.8 (1.3–5.9)	0.009	2.7 (1.2–6.1)	0.018
Hypotension	1.8 (0.7–4.8)	0.206	2.2 (0.8–5.8)	0.112
Education		0.050		0.012
Low	Ref		Ref	
Middle	1.0 (0.5–1.9)		0.7 (0.4–1.4)	
High	0.6 (0.3–1.1)		0.4 (0.2–0.8)	
Alcohol intoxication	0.9 (0.6–1.3)	0.565	1.2 (0.8–1.7)	0.463
ISS	1.03 (1.01–1.06)	0.026	1.02 (0.99–1.04)	0.156
AIS head	1.2 (1.0–1.3)	0.017	1.03 (0.90–1.12)	0.701
Extracranial injury	1.7 (1.1–2.7)	0.012	1.6 (1.0–2.4)	0.044
Marshall's CT		0.002		0.836
1	Ref		Ref	
2	1.9 (1.3–2.8)		1.0 (0.8–1.5)	
3–4	2.9 (1.2–7.6)		1.7 (0.7–4.1)	
5–6	15.5 (3.2–76.2)		8.5 (1.8–40.8)	
Facial fracture	1.4 (0.9–2.4)	0.147	1.3 (0.8–2.3)	0.307
EDH	1.0 (0.4–2.6)	0.986	0.3 (0.1–0.9)	0.033
tSAH	2.2 (1.5–3.3)	<0.001	1.3 (0.9–1.9)	0.224
Midline shift	7.8 (2.2–27.6)	0.013	3.2 (0.9–11.6)	0.070
Third ventricle obliteration	8.2 (2.6–26.4)	<0.001	3.2 (1.0–10.3)	0.050
Contusions	1.9 (1.2–3.1)	0.008	1.4 (0.9–2.3)	0.171
Petechial hemorrhage	2.0 (0.3–12.7)	0.473	0.5 (0.1–3.5)	0.527

Table 3. Multivariable Predictors of 3- and 6-Month Ordinal GOS-E.

Predictor	Common OR (95% CI) (3 months)	p value	Common OR (95% CI) (6 months)	p value
Age (per 10 years)	1.2 (1.1–1.4)	<0.001	1.2 (1.1–1.4)	<0.001
Cause		0.103		0.039
MV	Ref		Ref	
Fall	0.9 (0.6–1.4)		1.0 (0.6–1.6)	
Assault	1.9 (1.1–3.4)		2.0 (1.1–3.6)	
Struck by/strike against	1.1 (0.4–3.4)		0.5 (0.2–1.4)	
GCS		0.481		0.061
13	Ref		Ref	
14	0.8 (0.3–2.3)		0.4 (0.1–1.2)	
15	0.6 (0.2–1.7)		0.3 (0.1–0.9)	
No or one pupil reactive	1.0 (0.2–4.4)	0.974	2.1 (0.6–7.5)	0.253
Psychiatric medical history	2.2 (1.4–3.2)	<0.001	2.4 (1.6–3.7)	<0.001
Hypoxia	2.0 (0.9–4.4)	0.101	1.8 (0.7–4.2)	0.193
Hypotension	1.4 (0.5–3.6)	0.507	1.6 (0.6–4.1)	0.369
Education		0.032		0.016
Low	Ref		Ref	
Middle	0.8 (0.4–1.6)		0.7 (0.4–1.4)	
High	0.5 (0.2–1.0)		0.4 (0.2–0.9)	
ISS per point	1.02 (0.99–1.04)	0.250	1.00 (0.98–1.03)	0.759
Extracranial injury	1.7 (1.0–2.7)	0.045	1.5 (0.9–2.4)	0.105
tSAH	1.6 (0.9–2.9)	0.095	0.9 (0.5–1.5)	0.579
Mid-line shift	1.6 (0.3–8.6)	0.594	0.8 (0.1–5.2)	0.844
Contusion	1.3 (0.7–2.6)	0.404	1.6 (0.8–3.1)	0.176
Third ventricle obliteration	4.1 (0.8–20.6)	0.084	3.4 (0.6–20.2)	0.181

Table 4. Variable Importance Measure results based on cTMLE. Ѷ@Áˆ•cãj æֶˆ•Áæֶˆ^Á æֶbĕ•cˆåÁ‖‖Áֶ‖ֶ^æˇ‖ˆ^Á&[}֌ˇ}åãj*•Áæ}åÁֶàæֶֶˆåÁ•ãj*&[‖‖æֶ[‖æֶֶˆֶˆcˆåÁֶæֶãjˇ{Á‖ãֶ^‖ãֶ@[åÁ^•cãjֶæֶֶãj}ĕÜÖ‖Áֶã•\Ååã^‖^}&ĘÁJÍÃÔ‖ĘJÍÃÁ&[}֌ãj^}&ĘÁֶ^Áֶֶ‖çֶæֶֶֶ‖ÁŒ[[ÁÖ‖ÁŒ‖[‖ãj[[]¦‖cˆãjĘ

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Characteristic	cTMLE [95%CI]
Pãֶ¢‖‖ˆÁ֌‖P^] æֶֶֈ֌ãֶ^æˆ^Á	ֈֈ‖FֈֈÁֈֈ‖‖ֈGֈֈÁֈֈ‖ֈHֈֈ
Pãֶ¢‖‖ˆÁ֌‖•&@ֶֶֶֈ֌ãֶ^æˆ^Á	ֈֈ‖‖‖HÁֈֈ‖FֈֈÁֈֈ‖ֈ€ֈֈ
Ú‖ãֶ‖ÁֶÓֶÁ	ֈֈ‖ֈHֈÁֈֈ‖ֈ‖Áֈֈ‖ֈHֈ
Ú‖ãֶ‖ֈֶ^æֶˆ^ֶÁֶֶ֝@ֶֶֶ‖æˇ‖æֶˇ‖æֶˇֶˆÁ	€ֈ‖GֈÁֈֈ‖ֈGֈÁֈֈ‖ֈGֈ
Ò[֝‖[‖ˆ{^}Áֈֶæֶˆ•ֶֶֶֶֈֶֶ^ֶÁ֌‖Óֶֶֶֈֈ֌&ֈãj^Áç•Ęֶֈ&ãֶ^ĘÁ	ֈֈ‖ֈֈÁֈֈ‖FHֈÁֈֈ‖ֈFJֈ
Tæֶֶֈֶֶֶˆ•ֶֶ֌ãj^ֶ֌ÓֶÁֶ֌Tæֶ‖ֶֶֈֶֶֶˇ*ֶ֝*^c@‖ֈֶֶֶ‖‖{^}ĘÁ	€ֈ‖€ֈÁֈֈ‖ֈ‖Áֈֈ‖‖ֈ
Pˆ][cˆ‖•ãj}ĘÜÓÜĘJ€{P*ĘÁ	ֈֈ‖ֈֈGÁֈֈ‖FHֈÁֈֈ‖ֈ€ֈ
Væ&@&ֶֶֶֈֶֶֶˆ‖ĘÜ NF€€ֈĘj{ĘÁ	ֈֈ‖ֈֈÁֈֈ‖ֈHֈÁֈֈ‖ֈֈ
Væ&@‖]}^æֶĘÜ NFֈĘ&‖{ĘÁ	ֈֈ‖ֈGֈÁֈֈ‖ֈJֈÁֈֈ‖ֈGֈ
Pˆ][çãֶֶ‖ĘÜ ֈÜֶJֈÃĘÁ	€ֈ‖FֈÁֈֈ‖ֈֈÁֈֈ‖ֈHֈ
ÕÔÙÁ‖FֈÁ‖Ę‖FĘÁ	ֈֈ‖ֈֈÁֈֈ‖ֈֈÁֈֈ‖ֈHֈ
Ú[•ãֶֶ֌ֶ^åֶ‖‖*Á&‖^^}ãj*Á	ֈֈ‖ֈJֈÁֈֈ‖ֈֈÁֈֈ‖ֈֈ
Üֶccˆ‖ֶֶֶֶ&‖æֶ•ãֶֶֈֶֶֶ‖}Ę NGֈÁc•ĘĘֶGÁ	ֈֈ‖ֈFֈÁֈֈ‖ֈGֈÁֈֈ‖ֈHֈ
Tæֶ•@ֶֶֶ‖&‖æֶ•ãֶֶֈֶֶֶ‖}Ę NFֈÁc•ĘĘֶFĘÁ	ֈֈ‖€ֈÁֈֈ‖FֈֈÁֈֈ‖ֈGֈ
ŒֈSSFÁ‖[‖ˆ{‖‖]@ֶ‖{ֈÁ ‖ֈ‖Ęֶֶֈc@‖‖•Á	ֈֈ‖ֈֈֈÁֈֈ‖ֈJֈÁֈֈ‖ֈֈ
Œֈ[ֶֶÖÁ‖[‖ˆ{‖‖]@ֶ‖{ֈÁ ֶÓֈGֈֈֈ‖Ę‖Hֈ‖Ę‖ֈ‖ֈ‖Ęֶֶֈc@‖‖•Á	€ֈ‖ֈFÁֈֈ‖ֈHֈֈÁֈֈ‖€ֈֈ

ֈĘĘֶֶֈåֶֶֶֶֶ•ֶֈֈֶ֌ãֶֶֈֶֶֶ֌ãj}ãֶãj&^Ęֈֈ‖€ֈֈֈĘÁ

Task 3: Cleaning outcome data.

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Ú‖[*‖‖^••ĘÚ‖c‖[^åֶֈֶֶֶֶֶ@ֶֶ‖^^}&‖^æֶֶ^åֶֶֈֶֶ֌‖Ę åֶ^‖‖ֶֶֶ‖j}æֶĘj&[}•ãֶcֈ^}&ãֶ•Á&[‖‖^8cˆֶåĄ‖}ÁÁÁ •&@ֶֶ‖^‖ĘѶ@ֶ‖‖*‖‖^••Á@æֶֶ^}Áæֶã‖ֶֶ‖•ֈֶ^Áֶ[çֈ^æֶ‖{}*Áֶã@ֶֶ@ֶc@ֶ‖‖æֶֈ\ĘÁֶãֶֈ‖ÓֶֈÁFֈĘÁ Ѷ@ֶֶֈ֌ֈֶֈֈ‖@ֶֶֶ֌æֶֶ&‖^æֶãj*Áֈˆ•‖‖ֈֶָ‖Áֶ‖ˆc&[‖‖^•ֶֶֶ^å^Á‖‖‖çãֶ^åֶ‖æֶ^‖ãj}ãj*Á‖}Áæֶ^Á Gֈ‖Hֈֈֶֶ@ֶֈֶֶֶ&&@ֶֶֶ‖å^}‖[‖‖ˆÁ֌ãֶֈֶֶֶ**TRACK-TBI Summary Statistics for Data Curation"** **(Appendix A).** Ѷãj‖Á‖]‖‖‖ֶ֝•ֶ‖Ą‖ֈֶ‖çֈ•ֶֶֶֶֶֶֶ^‖^ֶֈ֌}&^Á֝ˇֶֈֶ^‖Á֌‖‖Ąֈֈ‖çֈ•cãֶæֶֶֶ‖•Á&[}֝ˇ&ãj*Á æ}æֶ‖•ˆ•ֈֶֶֶֶֶ*‖@ֶֶֶÁ Œֈ SֈֈÜֶÖֈֈÓֶÁֈj‖‖ֈÖæֶæֶֶֶ^cĘÁ

Task 4: Outcome analyses.

Ù‖ àæֶֈ\ĘFֈÖ^•&ֈj‖‖ã‖ãֈc^Áֶæֶãֈ‖æֶֶֶ•æֶֈ åÁֶæֶãֈ‖æֶֈֈֶֶ^•ˇ{]ֈ‖Áֈ‖}Áֈ‖^•ãj*ĘÁ

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Ú‖[*‖‖^••ĘĘÁ Y^åֶֶ^Áֶ‖ æֶ‖j*Á‖‖[*‖‖^••Áֶã@ֶֶ‖‖åֶֶ^•&ֈj‖‖ãֈc^Áֶæֶãֈ‖æֶֶֶ•æֶֈ åÁֶæֶãֈ‖æֶֈֈֶֶ^•ˇ{]ֈ‖ֈֶֶ}Á ֶ•ֶ‖j*Ęֶֈֈ֌‖[{^æֶֶ å֌ֈֶֶ‖@ֶ‖ã‖ãֈãֈ^ֶ‖[‖åֶ•Áֶֶֶֶֶֶ‖‖ֶֈֶ‖}^æ֌Áֶã@ֶֈֶֶ‖‖ֶ‖}^ֈָ‖åֶֶ ֈֶ^ֈ‖‖&‖ã‖ ֈ^Á]‖[çãֶֈֶåֶֶֶ‖åֶֈֶֶֶ‖@ֶֈֶ^ֈ‖‖‖‖Ùˇ àæֶ‖j\•Áֈֶֈֈ åÁ‖ĘÁ

Subtask 2: Ęֈ]ˇ ֈֈ֌‖}Á‖‖[ֈãj•ãj*Áçֈ֝ˇ^•ĘÁ

Ú‖[*‖‖^••ĘĘÁ Y^åֶֶ^ֈ^ˆ^}^ֶ^æֶ‖*Áֶֈֈ֌Ÿ‖‖‖æ&&[}•Á‖‖Á‖ã•ãj*Áçֈ֝ֈ^•æֶֶ åֶֈֶֶ‖[ˆ‖ãj*ֈֶֶֈֈֶֶֶc֝ˇ֌‖Á æֈֈ][ֶֈ֌&•ֈ‖j‖æ^ֶֈ֌ֈֶֈֈ֌ֈֈ֌ã•ãj*Å}••Ęֈֈ‖Á

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Table 5. Descriptive statistics, multivariate analysis of variance, and principal component analysis of multiple imputations for missing variable.

A

Variable	Groups	Test	Sig.
Age	M/I (n=282) Comp (n=263)	Mann-Whitney U Test	.012*
GCS	M/I (n=280) Comp (n=263)		.874
GOS-E	M/I (n=118) Comp (n=263)		.160
CT Pathology	M/I (n=282) Comp (n=263)	Chi-Squared	.050*

B

Variable	Variable Type	F	Sig.
Age		.396	.949
CT Pathology	Baseline	.190	.997
GCS		.004	1.000
GOS-E	GOS-E	.440	.927
BSI-18 Som		.066	1.000
BSI-18 Dep		.141	.999
BSI-18 Anx	Psychosocial	.135	.999
SWLS	Factor (PC 1)	.089	1.000
RPQ-3		.163	.998
RPQ-13		.101	1.000
PCL-C		.222	.994
CVLT Trials 1-5		.285	.985
CVLT SDFR		.351	.967
CVLT SDCR	Verbal Memory (PC 2)	1.107	.352
CVLT LDFR		.726	.701
CVLT LDCR		.620	.798
CVLT Free Intrus	Recall Error	1.072	.380
CVLT Cued Intrus	(PC 3)	.463	.914
WAIS	Processing	.721	.705
TMT	Speed (PC 4)	.185	.997

C

Factor Pattern Matching Index	Psychosocial Factors (PC 1)	Verbal Memory (PC 2)	Recall Error (PC 3)	Processing Speed (PC 4)
[1]r	.999	.997	.993	.989
[2]RMS	.000	.002	.001	.001
[3]CC	.999	.997	.993	.989
[4]s	1.000	1.000	1.000	1.000

Non Imputed PCA vs. Imputation Iteration 1 PCA

D

Factor Pattern Matching Index	Psychosocial Factors (PC 1)	Verbal Memory (PC 2)	Recall Error (PC 3)	Processing Speed (PC 4)
r	.999	.998	.997	.993
RMS	.000	.001	.000	.000
CC	.999	.998	.997	.992
s	1.000	1.000	1.000	1.000

Non Imputed PCA vs. Imputation Iteration 2

E

Factor Pattern Matching Index	Psychosocial Factors (PC 1)	Verbal Memory (PC 2)	Recall Error (PC 3)	Processing Speed (PC 4)
r	.999	.998	.993	.984
RMS	.000	.001	.001	.001
CC	.999	.999	.993	.984
s	1.000	1.000	1.000	1.000

Non Imputed PCA vs. Imputation Iteration 3 PCA

F

Factor Pattern Matching Index	Psychosocial Factors (PC 1)	Verbal Memory (PC 2)	Recall Error (PC 3)	Processing Speed (PC 4)
r	.999	.997	.996	.986
RMS	.000	.002	.000	.001
CC	.999	.997	.995	.986
s	1.000	1.000	1.000	1.000

Non Imputed PCA vs. Imputation Iteration 4 PCA

G

Factor Pattern Matching Index	Psychosocial Factors (PC 1)	Verbal Memory (PC 2)	Recall Error (PC 3)	Processing Speed (PC 4)
r	.998	.997	.994	.994
RMS	.000	.002	.001	.000
CC	.998	.997	.993	.994
s	1.000	1.000	1.000	1.000

Non Imputed PCA vs. Imputation Iteration 5 PCA

H

Factor Pattern Matching Index	Psychosocial Factors (PC 1)	Verbal Memory (PC 2)	Recall Error (PC 3)	Processing Speed (PC 4)
r	.999	.997	.994	.994
RMS	.000	.002	.001	.000
CC	.999	.997	.993	.994
s	1.000	1.000	1.000	1.000

Non Imputed PCA vs. Imputation Iteration 6 PCA

I

Factor Pattern Matching Index	Psychosocial Factors (PC 1)	Verbal Memory (PC 2)	Recall Error (PC 3)	Processing Speed (PC 4)
r	.999	.997	.994	.994
RMS	.000	.002	.001	.000
CC	.999	.997	.994	.994
s	1.000	1.000	1.000	1.000

Non Imputed PCA vs. Imputation Iteration 7 PCA

J

Factor Pattern Matching Index	Psychosocial Factors (PC 1)	Verbal Memory (PC 2)	Recall Error (PC 3)	Processing Speed (PC 4)
r	.997	.969		
RMS	.000	.005		
CC	.997	.973		
s	1.000	.833		

†Non Imputed PCA vs. Imputation Iteration 8 PCA

K

Factor Pattern Matching Index	Psychosocial Factors (PC 1)	Verbal Memory (PC 2)	Recall Error (PC 3)	Processing Speed (PC 4)
r	.999	.998	.996	.985
RMS	.000	.002	.000	.001
CC	.999	.998	.996	.984
s	1.000	1.000	1.000	1.000

Non Imputed PCA vs. Imputation Iteration 9 PCA

L

Factor Pattern Matching Index	Psychosocial Factors (PC 1)	Verbal Memory (PC 2)	Recall Error (PC 3)	Processing Speed (PC 4)
r	.998	.998	.995	.994
RMS	.000	.002	.001	.001
CC	.998	.998	.995	.994
s	1.000	1.000	1.000	1.000

Non Imputed PCA vs. Imputation Iteration 10 PCA

(A) Pre-imputation descriptive statistics shows some differences in baseline variables between Missing/Incomplete Outcomes group (M/I) and Complete Outcomes group (Comp) (B) After imputation, multivariate analysis of variance (MANOVA) demonstrates no significant differences in baseline and outcome variables between the original and imputed datasets. (C-L) PCA of the non-imputed data was not measurably different from any of the imputed PCAs. * $p \leq 0.05$ level. †The PCA from imputation iteration 8 resulted in 3 PCs, with the 3rd component being an aggregate of PC 3 and PC 4. In order to maintain consistency across domains, factor pattern matching statistics were only performed for components 1 and 2.
1--the Pearson's product moment correlation coefficient. 2--the root mean square difference in PC loadings. 3--the coefficient of congruence. 4--the salient similarity index.

Figure 4. Path Diagrams illustrating the four principal components.

A
Psychosocial Factors
BSI-18 Anx
.853
BSI-18 Dep
.832
-.627
SWLS
BSI-18 Som
.783
PC 1
.663
RPQ-3
.884
PCL-C
.864
RPQ-13
B
Verbal Memory
CVLT Trials 1-5
.864
CVLT LDCR
.931
.915
CVLT SDFR
PC 2
.930
CVLT LDFR
.937
CVLT SDCR
C
Recall Error
CVLT Free Intrus
.920
PC 3
.852
CVLT Cued Intrus
D
Processing Speed
TMT
-.852
PC 4
.796
WAIS

Each outcome variable's principal component score (arrows) positively (red) or negatively (blue) loads onto circles representing principal components 1-4: (**A**) Psychosocial Factors, (**B**) Verbal Memory, (**C**) Recall Error, and (**D**) Processing Speed.

The path diagrams (Fig. 4A-D) show all PC loadings gated at 0.5, the cut-off used in naming the PCs. Note that Psychosocial Factors were measured with all self-report measures including BSI-18 Somatization, BSI-18 Depression, BSI-18 Anxiety, SWLS, RPQ-3, RPQ-13, PCL-C. Verbal Memory was measured with CVLT-II Trials 1-5, Short Delay Free and Cued Recall, Long Delay Free and Cued Recall. Recall Error was measured with CVLT Free and Cued Recall Intrusions. Processing Speed was measured with TMT B-A, WAIS-PSI.

Subtask 5: Perturbation and subsampling analysis to assess model robustness and discriminant validity of outcome patterns.

Progress: This work is underway. Cooper et al. contains a variety of perturbation analyses including bootstrapping, feature sub-selection, multiple imputation and pattern matching across enrollment sites. The results indicate that we are identifying stable outcome patterns that replicate across a variety of data conditions.

The correlation matrix of all outcome variables (Table 6) identifies considerable correlations among multiple testing variables indicating that multiple tests may measure similar outcome domains. To assess the multidimensional structure of TBI outcomes we performed principal component analysis, a well-established approach that combines pattern detection with dimensionality reduction.

Table 6. Correlation Matrix of Core Outcome Variables.

	BSI-18 Som	BSI-18 Dep	BSI-18 Anx	SWLS	RPQ-3	RPQ-13	PCL-C	CVLT Trials 1-5	CVLT SDFR	CVLT SDCR	CVLT LDFR	CVLT LDCR	CVLT Free Intrus	CVLT Cued Intrus	WAIS	TMT
[1]BSI-18 Som	1	.584	.615	-.389	.553	.643	.621	-.149	-.123	-.070	-.117	-.076	.098	.124	-.192	.209
[2]BSI-18 Dep	.584	1	.729	-.614	.351	.659	.689	-.137	-.143	-.051	-.124	-.084	.114	.087	-.209	.180
[3]BSI-18 Anx	.615	.729	1	-.413	.447	.659	.735	-.036	-.058	.047	-.029	.029	-.116	.064	-.083	.105
[4]SWLS	-.389	-.614	-.413	1	-.229	-.464	-.500	.060	.028	-.018	.008	.013	-.021	-.092	.144	-.085
[5]RPQ-3	.553	.351	.447	-.229	1	.644	.552	-.140	-.061	-.015	-.063	-.042	.090	-.010	-.207	.166
[6]RPQ-13	.643	.659	.659	-.464	.644	1	.782	-.281	-.213	-.145	-.201	-.175	.108	.099	-.249	.246
[7]PCL-C	.621	.689	.735	-.500	.552	.782	1	-.167	-.170	-.090	-.136	-.091	-.106	.100	-.213	.148
[8]CVLT Trials 1-5	-.149	-.137	-.036	.060	-.140	-.281	-.167	1	.804	.778	.766	.788	-.118	-.296	.439	-.247
[9]CVLT SDFR	-.123	-.143	-.058	.028	-.061	-.213	-.170	.804	1	.835	.851	.826	-.074	-.351	.371	-.235
[10]CVLT SDCR	-.070	-.051	.047	-.018	-.015	-.145	-.090	.778	.835	1	.859	.900	-.140	-.301	.333	-.255
[11]CVLT LDFR	-.117	-.124	-.029	.008	-.063	-.201	-.136	.766	.851	.859	1	.892	-.165	-.354	.342	-.228
[12]CVLT LDCR	-.076	-.084	.029	.013	-.042	-.175	-.091	.788	.826	.900	.892	1	-.154	-.363	.382	-.247
[13]CVLT Free Intrus	.098	.114	.097	-.116	-.021	.090	.108	-.106	-.118	-.074	-.140	-.165	1	.667	-.085	-.053
[14]CVLT Cued Intrus	.124	.087	.064	-.092	-.010	.099	.100	-.296	-.351	-.301	-.354	-.363	.667	1	-.124	-.030
[15]WAIS	-.192	-.209	-.083	.144	-.207	-.249	-.213	.439	.371	.333	.342	.382	-.085	-.124	1	-.507
[16]TMT	.209	.180	.105	-.085	.166	.246	.148	-.247	-.235	-.255	-.228	-.247	-.053	-.030	-.507	1

Heat map showing bivariate correlation matrix of all CDE CORE outcome variables. Correlation coefficients are on a scale of -1 (negative correlation, in blue) to 1 (positive correlation, in red). Stronger correlations likely reflect redundancies amongst scales. [1]Brief Symptom Inventory – 18 Somatization Subscale, [2]Brief Symptom Inventory – 18 Depression Subscale, [3]Brief Symptom Inventory – 18 Anxiety Subscale, [4]Satisfaction With Life Survey, [5]Rivermead Post Concussive Questionnaire – 3 Item Subscale, [6]Rivermead Post Concussive Questionnaire – 13 Item Subscale, [7]Post Traumatic Stress Disorder Checklist – Civilian Version, [8]California Verbal Learning Test (CVLT) – Trial 1 to 5, [9]CVLT – Short Delay Free Recall, [10]CVLT – Short Delay Cued Recall, [11]CVLT – Long Delay Free Recall, [12]CVLT – Long Delay Cued Recall, [13]CVLT – Free Recall Intrusions, [14]CVLT – Cued Recall Intrusions, [15]Wechsler Adult Intelligence Scale – Processing Speed Index, [16]Trailmaking Test – Trial B minus Trial A.

Task 5: Diagnostic modeling.

Subtask 1: Integrative exploratory factor analysis (EFA)/Non-linear PCA to integrate outcome domains from Aims 1-3.

Progress: This work will proceed on schedule during Year 2.

Subtask 2: Confirmatory factor analysis (CFA) to begin testing generalization and test validity of the diagnostic battery.

Progress: This work will proceed on schedule during Year 2.

Subtask 3: CFA model re-specification and fit optimization.

Progress: This work will proceed on schedule during Year 2.

Subtask 4: Develop structural equation model.

Progress: This work will proceed on schedule during Year 2.

Aim 2. To identify neuroimaging biomarkers for diagnosis and prognosis in TBI

Task 1. Extract imaging common data elements (CDE) from CT and MRI exams.

Progress: All CT and MRI exams have been interpreted by a board-certified neuroradiologist, and pathoanatomic lesions have been recorded using the NIH Common

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Task 2. Quantitative CT.

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Figure 5. Comparison of software and physician intrepreation of CT findings.

Task 3. Diffusion tensor imaging (DTI) and resting-state fMRI preprocessing.

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Task 4. DTI and resting-state fMRI analysis using voxelwise nonparametric permutation testing.

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	Demographic, clinical, socioeconomic				Day-of-injury head CT					Early brain MRI (11.2 ± 3.3 days postinjury)		
	Age	Education (years)	Neuropsychiatric history	History of alcohol or drug problem	Nondepressed calvarial or skull base fracture	EDH	SDH	SAH	Any CT contusion	Any MRI contusion	Any MRI T2* evidence of hemorrhagic axonal injury[b]	Any DTI axonal injury (≥1 ROI with FA > 2.2 SDs below control-group mean)
3-month GOS-E (N=70)	−0.30* p=0.013	0.27* p=0.02	−0.27* p=0.03 (18 pos.)	−0.12 p=0.34 (34 pos.)	−0.12 p=0.33 (12 pos.)	−0.08 p=0.54 (3 pos.)	−0.23 p=0.06 (9 pos.)	−0.28* p=0.02 (6 pos.)	−0.22 p=0.07 (5 pos.)	−0.36[†] p=0.003 (11 pos.)	−0.12 p=0.34 (24 pos.)	−0.34[†] p=0.004 (23 pos.)
6-month GOS-E (N=65)	−0.18 p=0.16	0.31* p=0.011	−0.30* p=0.02 (17 pos.)	−0.18 p=0.15 (31 pos.)	−0.13 p=0.32 (10 pos.)	0.01 p=0.97 (2 pos.)	−0.17 p=0.18 (7 pos.)	−0.20 p=0.11 (5 pos.)	−0.19 p=0.14 (4 pos.)	−0.19 p=0.12 (9 pos.)	−0.03 p=0.84 (22 pos.)	−0.25* p=0.04 (20 pos.)
Abnormal TMT B (>2 SDs above age-adjusted mean) at 6 months (N=61)	0.11 p=0.42	−0.18 p=0.17	−0.02 p=0.90 (16 pos.)	0.01 p=0.94 (30 pos.)	−0.14 p=0.27 (9 pos.)	−0.11 p=0.40 (2 pos.)	0.02 p=0.88 (7 pos.)	0.09 p=0.47 (5 pos.)	−0.16 p=0.22 (4 pos.)	0.07 p=0.61 (9 pos.)	0.17 p=0.18 (22 pos.)	0.32* p=0.011 (19 pos.)
6-month RPQ-3 (N=65)	0.23 p=0.07	−0.23 p=0.06	0.36[†] p=0.003 (17 pos.)	0.25* p=0.045 (31 pos.)	−0.12 p=0.32 (10 pos.)	−0.21 p=0.09 (2 pos.)	0.11 p=0.37 (7 pos.)	0.01 p=0.93 (5 pos.)	0.07 p=0.56 (4 pos.)	0.03 p=0.84 (9 pos.)	−0.10 p=0.45 (22 pos.)	0.18 p=0.14 (20 pos.)
6-month RPQ-13 (N=65)	0.26* p=0.04	−0.28* p=0.02	0.31* p=0.013 (17 pos.)	0.16 p=0.20 (31 pos.)	0.02 p=0.85 (10 pos.)	−0.07 p=0.60 (2 pos.)	0.19 p=0.14 (7 pos.)	0.16 p=0.21 (5 pos.)	0.21 p=0.10 (4 pos.)	0.12 p=0.34 (9 pos.)	0.02 p=0.85 (22 pos.)	0.29* p=0.02 (20 pos.)

fMRI preprocessing and analysis.

Results.

a.
-57
-6
23
h.
-63
-7
27
b.
-34
-45
-7
i.
-38
18
42
c.
-42
-55
-27
j.
27
-31
28
d.
-20
3
39
k.
2
-33
44
e.
17
26
-7
l.
-38
3
33
f.
-25
-31
28
m.
1
35
12
g.
-72
16
-1
n.
4
10
-7

Figure 6. Fourteen resting state functional connectivity networks examined for differences between mTBI patients and controls, including independent components corresponding to the default mode network (*a, h i*), the auditory/temporal network (*b*), the cerebellar network (*c*), the motor network (*d*), the ventromedial prefrontal network (*e*), the somatosensory/parietal network (*f*), the visual network (*g*), the executive control network (*j, m*), the left (*k*) and right (*l*) attention networks, and the salience network (*n*).

Figure 7. Statistically significant group differences in functional connectivity between mTBI patients and controls (*blue*) within five different resting state networks (*copper*), including the executive control network (*a, c*), motor network (*b*), ventromedial prefrontal network (*d*), auditory/temporal network (*e*) and the default mode network (*f*).

Task 5. DTI and fMRI region-of-interest (ROI) analysis.

Task 1. Biospecimen Proteomic Analyses.

Task 2. Biospecimen Genomic Analyses

Association of COMT Genotype with PTSD

Figure 8.

	PTSD		
	No	Yes	

COMT Genotype

Association of COMT Genotype with PTSD in the Presence of Prior Psychiatric History

In order to test for the association of COMT G/G in the presence of prior psychiatric history, we took a two-tiered approach. First, we performed a univariable logistic regression of each predictor with PTSD as the dependent variable **(Table 8A)**. COMT G/G had a univariable odds ratio (OR) of 3.6 (95% CI 1.3-9.7, p=0.011), and explained between 6.1% (Cox and Snell pseudo-X2 (CSR2) and 8.9% (Nagelkerke pseudo-R2 (NR2)) of the variability in PTSD. Prior psychiatric history had a univariable OR of 5.5 (95% CI 2.1-14.2, p=0.000), and explained 12.3% (CSR2) to 17.9% (NR2) of the variability in PTSD. We confirmed that there was no interaction between COMT G/G and prior psychiatric history (p=0.093, Pearson X2).

Table 8A. Univariable Association of COMT and Prior Psychiatric History with Six-Month PTSD.

Predictor	Univariable OR (95% CI)	Predictor Sig. (p)	Cox & Snell Pseudo-R^2	Nagelkerke Pseudo-R^2
COMT A	0.3 (0.1-0.7)	0.011	6.1%	8.9%
Prior Psych Hx	5.5 (2.1-14.2)	4.35E-4	12.3%	17.9%

We then performed a multivariable logistic regression with COMT G/G and prior psychiatric history as predictors, and PTSD as the dependent variable **(Table 8B)**. This model was highly statistically significant (p=0.000) and explained between 15.9% (CSR^2) and 23.2% (NR^2) of the variability in PTSD which was an improvement from both COMT and prior psychiatric history alone. Both COMT G/G and prior psychiatric history emerged as statistically significant predictors of PTSD. Although prior psychiatric history emerged as the stronger predictor with a multivariable OR of 5.0 (95% CI 1.9-13.3, p=0.002), COMT was able to survive the regression with a multivariable OR of 3.1 (95% CI 1.1-8.9, p=0.037).

Table 8B. Multivariable Association of COMT and Prior Psychiatric History with Six-Month PTSD

Predictor	Multivariable OR (95% CI)	Predictor Sig. (p)	Model Sig. (p)	Cox & Snell Pseudo-R^2	Nagelkerke Pseudo-R^2
COMT A	0.3 (0.1-0.9)	0.037	1.48E-4	15.9%	23.2%
Prior Psych Hx	5.0 (1.9-13.3)	0.001			

Association of COMT on Secondary Outcome Measures

We assessed the association between COMT genotype on GOSE and WAIS-PSI. **Figure 9** shows a significant association between COMT and GOSE (p=0.041, Mann-Whitney U), with a one point IQR (7-8) for A-carriers compared to three points (5-8) for G/G. **Figure 10** shows a significant association between COMT and WAIS-PSI (F=7.141, p=0.009), with A-carriers composite scores at 103.6 (95% CI 100.4-106.7), which translates to performance between 55th to 63rd percentile [WAIS]. In contrast the mean composite score for G/G was 94.2 (95% CI 86.4-102.0), which falls at the 34th percentile.

Figure 9ÊÖãčãˇčą}Á-Á¦[àą4Á¦ˇč&[{^Á4&¦^•Á^ÁÕUÙÒÁã^ÁÔUTVÁˇ^}[ćʹ]^ÊÙãã}ãã&ą}&^Á
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ÕUÙÒÁÁ	FÍÁÇFÌÃDÁ	GÁÇÃDÁ	€Èˆ€ÍÁ
ÕUÙÒÁÁ	HɀÁÇHÌÃDÁ	ÏÁ ÇHɀÃDÁ	
ÕUÙÒÁÁ	HɀÁÇHÌÃDÁ	ÏÁ ÇÇÌÃDÁ	

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Figure 10. Association of COMT Genotype with Six-Month Processing Speed.

COMT and Processing Speed

Öãčãˇčą}Á-Á̃ŒUËÜÙÒ&[{][•ãˆ^&¦¦•^• Áˆ^ÁÔUTVÁˆ^ć[ćʹ]^ÊÙãã}ãã&ą}&^ÁÇDãÁæ•^••^åÁ
ˇ•ã*ÁŒPUXŒÊÇį̄¦Á^-^¦^}&^ÊÁ̃ŒUËÜÙÒ&ÌJÁÇH°åÃ́ą¬Ì®̈Ãˇ̃ą¬ÌÆF€€Áɱ€°̈́Ã́ˇ̃ą¬ÌÆ€ÍÁ
ÇHˇ̊åÃ́ą¬ÌÁˆ^Á̃ŒUËÜÙÒÁ^&@¦^¦^ÁÌ̃ˇ|čÁǫ̌¦|č¦|ãą^}&^Á̃Ù&ą4^ÁÊǫ̌ˇ¦c@Á̊åãçãą}Áˇ̊¦[&^••ãã*Áˇ̊]^^åÁ
Qåˆ^čLã̈́ąˆ^ÁỈ^¦&^}čą^Á
Á
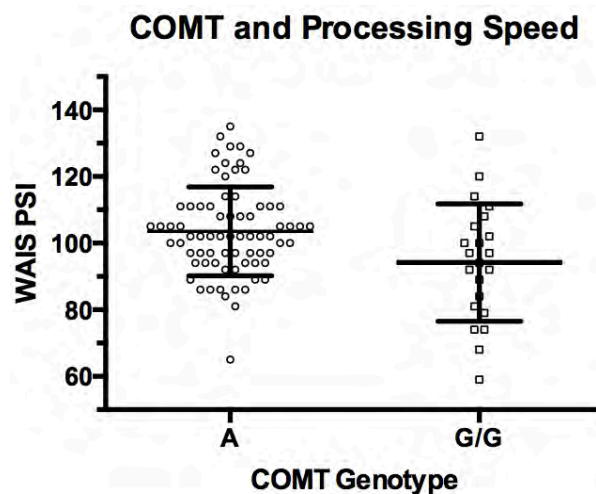
During the fourth quarter the following SNPs were sequenced (results in Tasks 4 and 5):
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Dopaminergic:
- Á Ü•FFɀ€ÍÎ ¦FÁ̃ąåÁ•ÍJHÌ€FÎÁ̃ąą^ÁÙÞÚ•Á ̃ą̃@ą̃Ác@ÁÕÜÖÖGÁˆ^}^Á̃cĉ̊ąÁ¦{Á̃ą̃4̃@ą̈́¦[à|[&Á ̃ą̃c@ą̃c@Áą̈́^æą̊^Áˆ^ˇ̌ˇ^}&^åÁŒPUSSFÁ̃•FÍ€€JÏÁ̃ąą^åÁ̃ą̃•^&ãąæ^Áą̃̃@ą̃[[¦&[*}ãąĉ^Á [ˇč&[{^Áæĉ^¦Á-Á́ÓÈÁ
- Á Ü•ÎˆGˈˆÏÁ̃ąą̃ÁÙÞÚÁˈ̃ą̃@ą̃c@ÁÕÜÖGÁˆ^}^Á@¦^ć@ąÁỖÁ̃ą¦|^¦Áą̃•^&ãąæ^•Á̃ą̃@ą̈́&|^æ^åÁ ÚVÙÒÁã\ÈÁ

Serotonergic:
- Á Ü•ÎˆHFFÁ̃ąą̃ÁÙÞÚÁ̃ą̃@ą̃c@ÁPVÜGŒÁˆ^}^ÁÁ́c@Á^¦[ć}^¦*&Áąąæ̂@¸æêÁ́c@ąą̃Á[••ãą|̂^Á æ•[&ãąæ^•Á̃ą̃@ÁÚVÙÒÁæ̂c^¦Áčąˆ̃{ æÍUT ŒÆFJÌIGFÎÁ́È

- Á Ü•ÏJÍÍF/æ桿ÙÞÚÁ æc@æÁ@ÁŠÔÎŒÁ^}^c@æÁ•[&æ桕 Á æc@Áå^]¦•••æ̧}/æ̧åÁ ÚVÙÖÉÁ

Neurodegenerative:

- Á Ü•ÎÇÍ/æ桿ÙÞÚÁ æc@æÁ@ÁÖÞØÁ^}^È/@ÁŒæ¦|^|^&}^•/æ̧&^æ^åÁ㸕\Á[Á[¢¦Á •\ã|Á]毿{^cÚTŒÁFÏÍÍ€G€/æ̧åÁd[ç^|•ã̧}É

Additional SNPs based on current literature:

BCL2

- Á Ü•FÏÍÎÍJ/æ桿ÙÞÚÁ æc@æÁ@ÁÔŠGÁ^}^Á @&@Á}&å•^/æ̧å¦[˵çãçæ̧åÁ[c˛ã̧/æ̧Á c@Á桕[]d˛•ã̧æ@̧æÈ/@Á ÞÚÁ•[&æ桕 Á æc@Á[[¦^Á̆c&{^Á æåÁ@¦Á {[¦æãc^ÁÕUÙ桕ç¦^ç¦^ÁÓÉ

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PARP-1

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Task 3. Data Analysis.
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Tasks 4 and 5. Prognostic and Diagnostic Modeling. ÁT˛|ãc毿æ^Áæŧ㸕&Á|˛å㬵*ÁÚÔŒÁ æ̧åÁÙÒTÁĊæ̧Á FÉÁå^åÁÖVæ̧åÁTÜŒÁ毿ã̧*Áæ毿Ċæ̧ÁGÁã|Á毿^^+[{^å/æ̧¦^/æ̧cÁ^•ææ̧|ã@Á {[å^|•Á[¦Á^&ã̂&åã̂毿}[•cÁ&|æ•ã̂&毿æ̧}•Áæ̧åÁ¦[*}[•cÁæã̧{æˀ^¦•ÉÁ

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Ú¦[*¦^••Á**Figure 11/**||•c̈æ^•Á@^^˛|c̈Á-Áã̧}[•cÁæ̧åÁ¦[*}[•cÁ[[å^|ã̧*Á@毿æ̧Á ã̧c˛*¦毿^•åæ毿&[••å||^}[{ã/æ̧åÁ̆c&{^Á^毿̆¦^•ÉÁ

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Figure 11.

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Table 9. Multivariate Tests[a]

Table 10. Tests of Between-Subjects Effects

Table 11. Correlations

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4. KEY RESEARCH ACCOMPLISHMENTS

- Publication of the first study to compare DTI in individual mild TBI patients to conventional imaging, clinical, and demographic/socioeconomic characteristics for outcome prediction. DTI demonstrated utility in an inclusive group of patients with heterogeneous backgrounds, as well as in a subset of patients without neuropsychiatric or substance abuse history. Significant predictors of 6-month GOS-E included region of interest with severely reduced fractional anisotropy, neuropsychiatric history, and years of education. For the subset of 37 patients lacking neuropsychiatric and substance abuse history, MRI surpassed all other predictors for both 3- and 6-month outcome prediction (Yuh et al).
- Reliable outcome prediction in mild TBI is important for clinical practice. Identifying patients at increased risk of unfavourable outcome permits targeting closer observation and early intervention, which may reduce the psychological burden of injury on the patients, and the related economic burden on society. Our study demonstrates that existing models for mild TBI perform unsatisfactorily. We tested 21 variables in ordinal analysis of 386 patients, which is 1 in 18 and thus reasonable from a statistical perspective. Although we have found some strong predictors of poor outcome, such as age and history of psychiatric condition, given the sample size, we consider the results of our prognostic analysis as hypothesis generating. These predictors will need further validation in ongoing prospective longitudinal studies, such as those that are part of the International TBI Research Initiative (Lingsma et al).
- In a broad range of patients with mild to severe TBI measurement of GFAP-BDP yielded a net benefit above clinical screening alone and a net reduction in unnecessary scans by 12 to 30%. Used in conjunction with other clinical information, rapid measurement of GFAP-BDP is useful in establishing or excluding the diagnosis of radiographically apparent intracranial injury throughout the spectrum of TBI. As an adjunct to current screening practices, GFAP-BDP may help avoid unnecessary CT scans without sacrificing sensitivity (McMahon).

5. CONCLUSIONS

We have demonstrated progress across all aims which are of significance to civilian and military TBI clinical care. We have successfully created an Information Commons for the TBI CDE domains across the injury spectrum from concussion to coma. Most importantly these biomarkers will be vital to the design of future clinical trials for TBI. For future plans during year 2 we are on target to complete the original tasks to conduct multivariate diagnostic and prognostic modeling across all aims.

6. PUBLICATIONS, ABSTRACTS AND PRESENTATIONS

Yuh EL, Cooper SR, Mukherjee P, Yue JK, Lingsma HF, Gordon WA, Valadka AB, Okonkwo DO, Schnyer DM, Vassar MJ, Maas AIR, Manley GT and the TRACK-TBI Investigators. Diffusion Tensor Imaging for Outcome Prediction in Complicated and Uncomplicated Mild Traumatic Brain Injury: A TRACK-TBI Study. J Neurotrauma 2014 Jul 9. PMID: 24742275

Lingsma HF, Yue JK, Maas AIR, Steyerberg EW, Okonkwo DO, Valadka AB, Gordon WA, Mukherjee P, Yuh EL, Puccio AM, Schnyer DM, Manley GT, TRACK-TBI Investigators. Outcome Prediction after Mild Traumatic Brain Injury: External Validation of Existing Models and Identification of New Predictors using the TRACK-TBI Pilot Study. J Neurotrauma 2014 Jul 15. PMID: 25025611.

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Ÿ˘^ÊRÈSÊÊÔ[]^¦ÊÙËÊÊÖæËŒʦ挿ãæÊÙÊÙ æ)* ÊSÈSÊÊ[¦æ)æ̂ŤÊ ÈÔÊÃã* •{æ̂PÈŒÊÁ
Ÿ˘@ŒÒÈŠÊÁ˘\@¦b^^ÁÙÊ˜æ̦æ毿ÁŒÉÔÊÊÖ[å[}ÊÙ ÈŒÊÙ\[}\¸[ÊÙÈŨÊÁæ)|^^ÊÙÈ̃ÈÔÈ
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7. INVENTIONS PATENTS AND LICENSES

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8. REPORTABLE OUTCOMES

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9. OTHER ACHIEVEMENTS

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10. REFERENCES

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11. APPENDICES

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TRACK-TBI
Summary Statistics
for Dataset Curation

v.2.0

December 2013

Age vs. Sex and Study Site
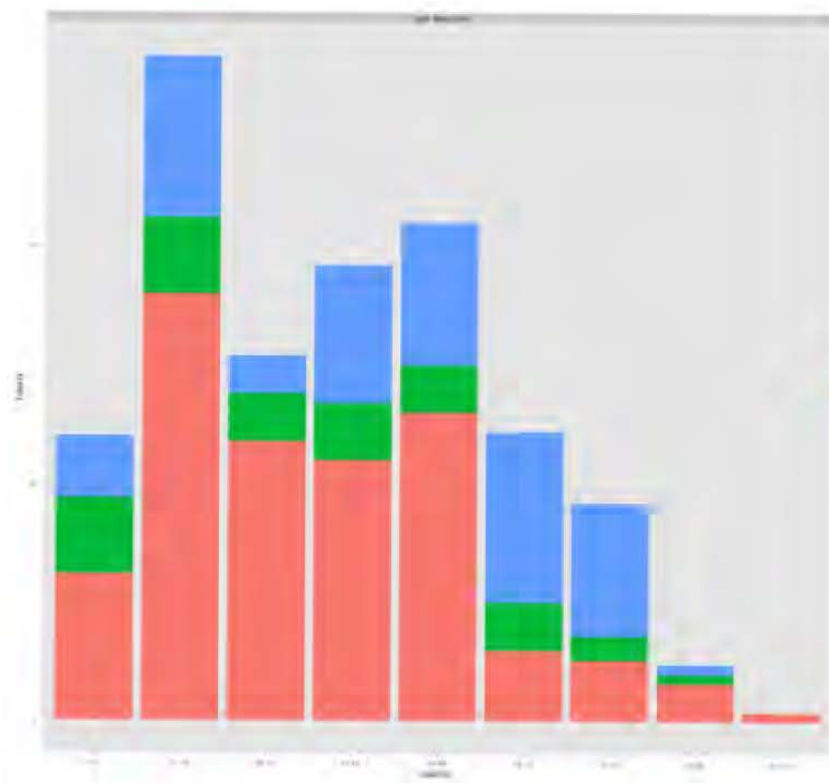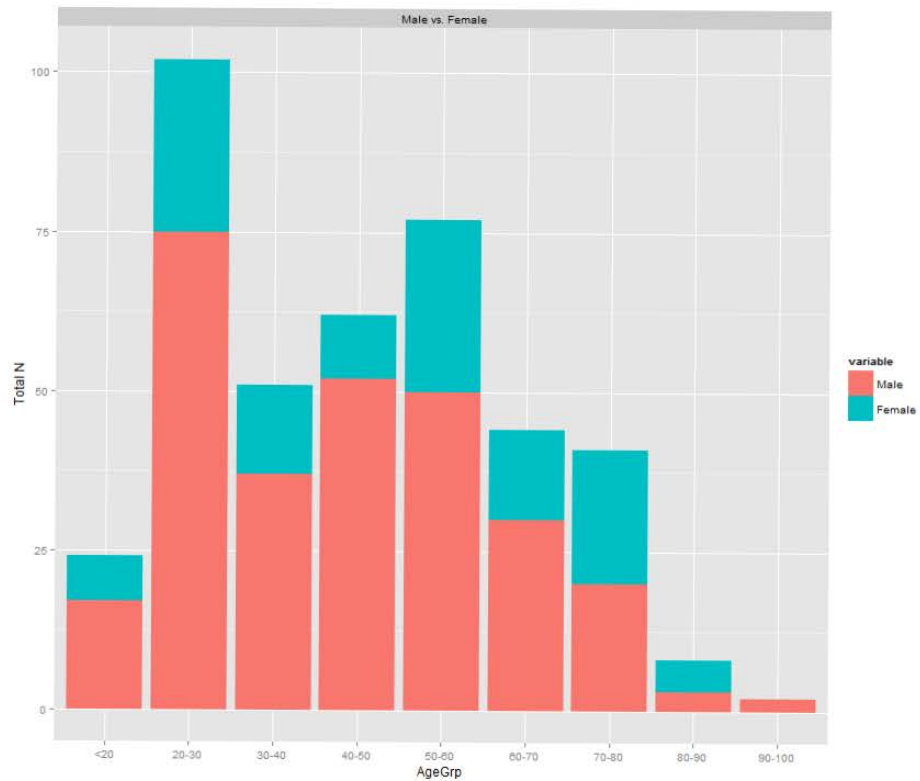
GCS at ED Arrival
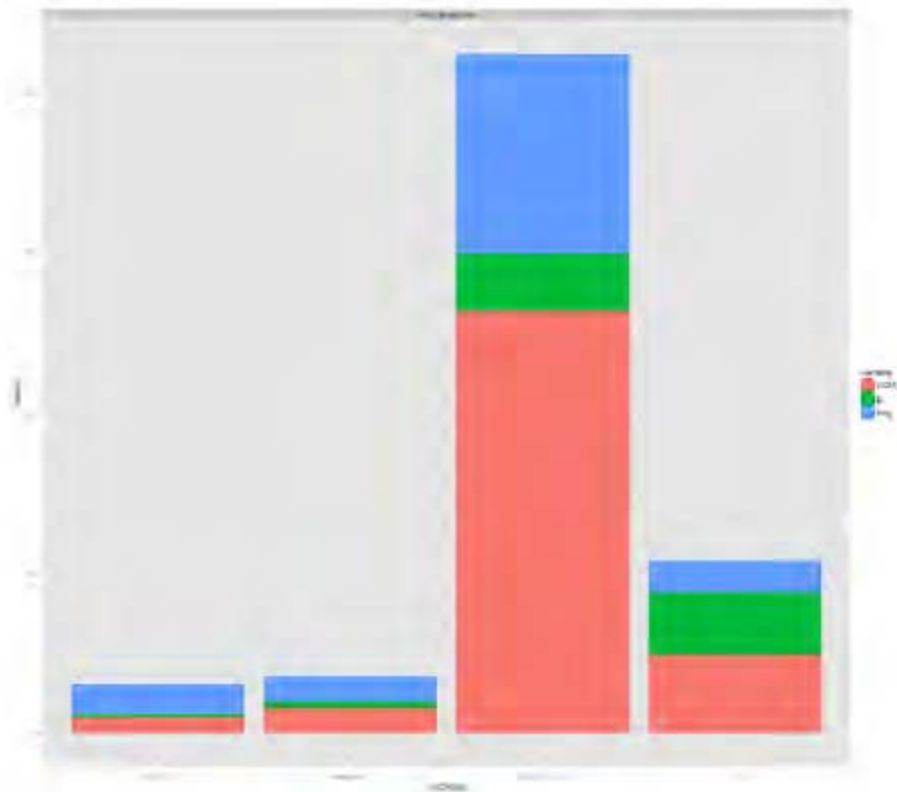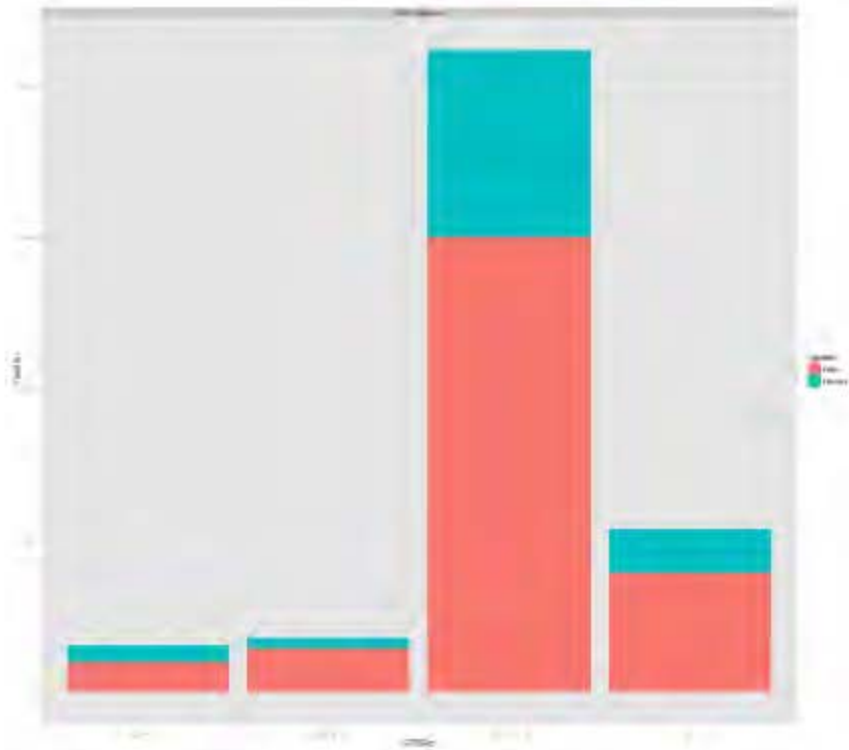
GOSE Month 3 and 6
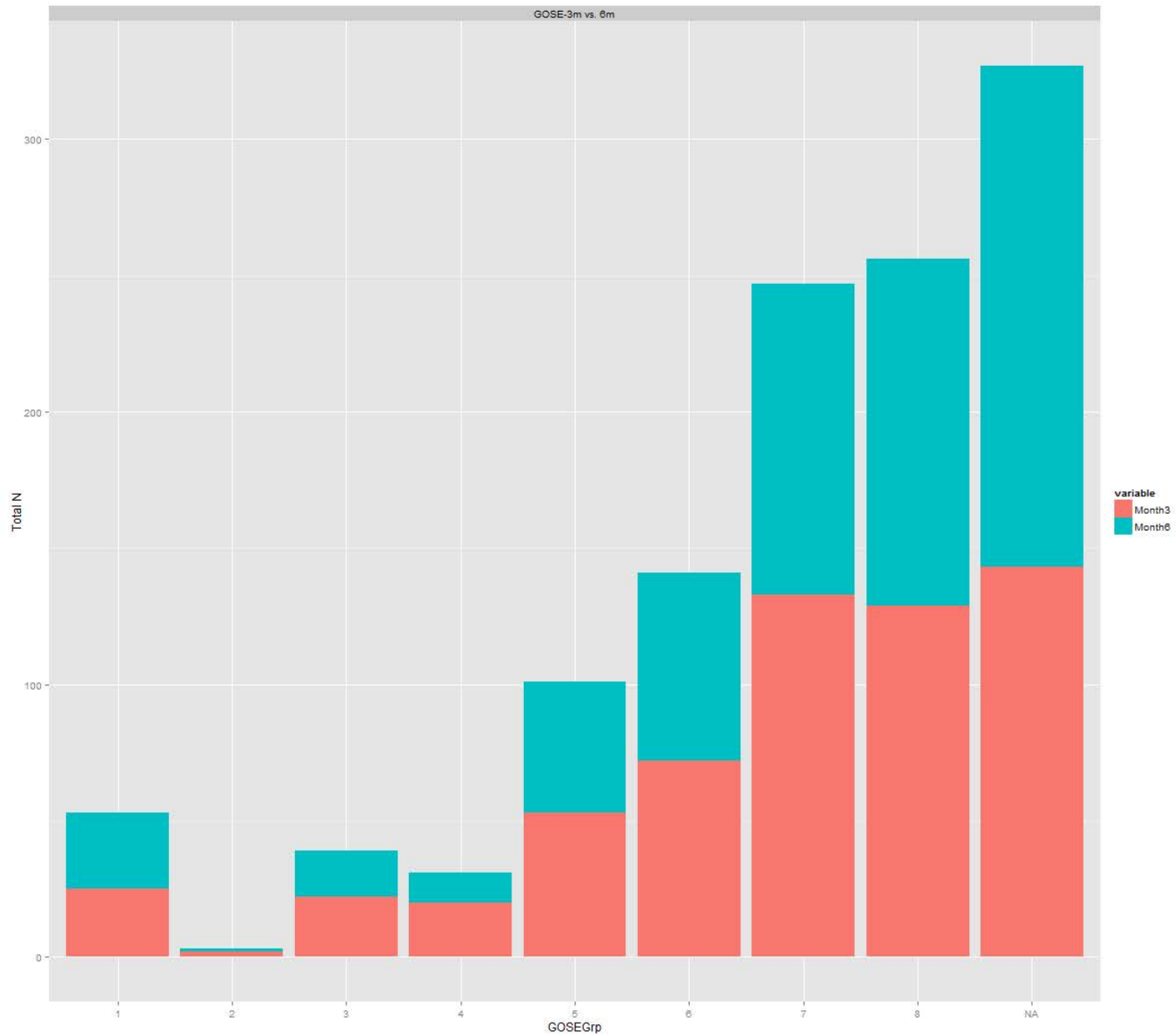
Baseline Summary

Parameter	Count	Mean	Median	Min	Max	SD	Missing/NA
Sex							
1 - Female	125						
2 - Male	286						
Age	411	44.698	44	17	94	18.814	0
School Education (Number of Years Completed)	374	14.072	14	2	24	2.935	37
Any Psychiatric History							
1 - No	288						
2 - Yes	123						
Alcohol Test (mg/100 ml Blood)	207	84.700	0	0	416	110.177	204
Arrival GCS Total Score	378	13.566	15	3	15	3.114	33
ISS Score Calculated	379	13.953	14	0	57	11.805	32
Previous TBI							
1 - Yes	83						
2 - NA	328						
GFAP Plasma Concentration (ng ml)	144	2.027	0.625	0.02	20.087	3.470	267
UCH L1 Plasma Concentration (ng ml)	133	0.286	0.183	0.03	2.918	0.363	278
ApoE							
1 - E2/E2	2						
2 - E2/E3	35						
3 - E2/E4	5						
4 - E3/E3	196						
5 - E3/E4	64						
6 - E4/E4	4						
7 - NA	105						

Follow-up Summary

Parameter	3-month				6-month			
	Count	Mean	Median	Missing/NA	Count	Mean	Median	Missing/NA
GOSE				143				184
1-Dead	25				28			
2-Vegetative State (VS)	2				1			
3-Lower Severe Disability (Lower SD)	22				17			
4-Upper Severe Disability (Upper SD)	20				11			
5-Lower Moderate Disability (Lower MD)	53				48			
6-Upper Moderate Disability (Upper MD)	72				69			
7-Lower Good Recovery (Lower GR)	133				114			
8-Upper Good Recovery (Upper GR)	129				127			
Neurological Assessment Overall Rating				160				217
1-Normal	154				126			
2	109				97			
3	80				67			
4	42				48			
5	29				22			
6-Very Different	25				22			
GSI T-score					339	54.67	64	260
RPQ-3					341	2.33	13.4	258
RPQ-13					341	2	11	258

Case Report Forms

- Subject
  - Demographics
  - Socioeconomic Adult
  - Socioeconomics Child
  - Military Service
  - Subject Notes/Informed Consent

- Medical History

- Injury History
  - Early & Late Presentation
  - Cause of Injury
  - AIS/ISS Injury Severity
  - LOC PTA
  - Screening for Previous TBI

- Hospital
  - Emergency Department
  - Hospital Admission /Discharge
  - Complications
  - Surgeries
  - Monitoring Devices

- Outcomes and Endpoints
  - Form Completion Status
  - Brief Symptom Inventory
  - Civilian PTSD Check List
  - CVLT
  - CHART-SF
  - Extended Glasgow Outcome Scale
  - Extended Glasgow Outcome Scale Pediatric
  - Functional Independence Measure
  - Neurological Assessment
  - Post Discharge & Outpatient Care
  - Rivermead Post-concussion Symptoms Questionnaire
  - Satisfaction with Life Scale
  - Trail Making Test and WAIS IV

Demographics

Patient Number [_____]

Form Completion Status
- ☐ In Progress
- ☐ Complete

Age [_____]

Sex
- ◯ Female
- ◯ Male

Country of Birth
- ☐ USA
- ☐ Mexico
- ☐ Canada

Country of Birth (not in list)
[_____]

Country of Residence
- ☐ USA
- ☐ Mexico
- ☐ Canada

Country of Residence (not in list)
[_____]

Primary Language [_____]

Primary Language (not in list)
[_____]

Ethnicity
- ☐ Hispanic or Latino
- ☐ Non Hispanic or Latino
- ☐ Unknown

Handedness
- ☐ Righthanded
- ☐ Lefthanded
- ☐ Both

Race
- ☐ Indian
  - ☐ South/Central American Indian
  - ☐ North American Indian
- ☐ Alaskan Native/Inuit
  - ☐ Alaskan Native
  - ☐ Intuit
- ☐ Asian
  - ☐ South Asian
  - ☐ Far Eastern Asian
- ☐ Black
  - ☐ African American
  - ☐ African
  - ☐ Afro Caribbean
- ☐ Native Hawaiian/Pacific Islander
  - ☐ Hawaiian
  - ☐ Pacific Islander
- ☐ White
  - ☐ North American
  - ☐ South American
  - ☐ European
  - ☐ Middle Eastern
  - ☐ White African
  - ☐ Oceanian

Unable to obtain information
- ☐ Refused
- ☐ Unknown by patient or family
- ☐ Discharged/expired before asked
- ☐ Other

Other Reason [_____]

Socioeconomics (1)

Number of years of school completed:

[_____]

Highest diploma/degree:
- ☐ None, not currently in school
- ☐ None, but currently in diploma or degree-oriented program
- ☐ Vocational training (no high school diploma or GED)
- ☐ GED
- ☐ High school diploma
- ☐ Vocational training (post high school)
- ☐ Associates degree
- ☐ Bachelors degree
- ☐ Masters degree
- ☐ Doctoral degree
- ☐ Unable to obtain information

Unable to obtain information
- ☐ Refused
- ☐ Unknown by patient or family
- ☐ Discharged/expired before asked
- ☐ Other
- Other Reason [_____]

Employment
- ☐ Working full time (35 hrs or more/week, at least minimum wage)
- ☐ Working 20-34 hrs/week, at least minimum wage
- ☐ Working less than 20 hrs/week, at least minimum wage
- ☐ Temporary/odd jobs/less than minimum wage jobs
- ☐ Special employment (sheltered workshop, supportive employment, job coach)
- ☐ Unemployed
- ☐ Other
- ☐ Not in paid workforce (including child, retired, student, homemaker, disabled pre-injury)
- ☐ Unable to obtain information

Unable to obtain information
- ☐ Refused
- ☐ Unknown by patient or family
- ☐ Discharged/expired before asked
- ☐ Other
- Other Reason [_____]

Socioeconomics (2)

Marital Status

- ☐ Single
- ☐ Married/living together/common law
- ☐ Separated
- ☐ Divorced
- ☐ Widowed
- ☐ Other

Unable to obtain information

- ☐ Refused
- ☐ Unknown by patient or family
- ☐ Discharged/expired before asked
- ☐ Other
- ☐ Other Reason [_____]

Current Student Status

- ☐ Full time student (diploma/degree oriented/2 courses or more)
- ☐ Part time student (diploma/degree oriented)
- ☐ Elementary school student (0-8th grade)
- ☐ Secondary school student (9-12th grade)
- ☐ Special education
- ☐ Vocational program
- ☐ Other
- ☐ None
- ☐ Unable to obtain information

Current Student Status Other [_____]

Unable to obtain information

- ☐ Refused
- ☐ Unknown by patient or family
- ☐ Discharged/expired before asked
- ☐ Other
  - Other Reason [_____]

Primary person(s) living with

- ☐ Alone
- ☐ Spouse (including common law partner)
- ☐ Parents
- ☐ Siblings
- ☐ Child/children
- ☐ Significant other partner
- ☐ Roommates/friends
- ☐ Other patients (in hospital/nursing home)
- ☐ Other residents
- ☐ Group living situation, boarding house
- ☐ Personal care attendant
- ☐ Military barracks
- ☐ Homeless
- ☐ Other (incl. correctional facility inmates)
- ☐ Unable to obtain information

Specify other resident [_____]

Unable to obtain information

- ☐ Refused
- ☐ Unknown by patient or family
- ☐ Discharged/expired before asked
- ☐ Other
  - Other Reason [_____]

Socioeconomics Child

LIVING SITUATION

Living with

- ☐ Parents
- ☐ Other family members
- ☐ Adoptive parents
- ☐ Foster case
- ☐ Other
- ☐ Unable to obtain information

Unable to obtain information

- ☐ Not Allowed
- ☐ Unknown by patient or family
- ☐ Discharged/expired before asked
- ☐ Other

  Other Reason [   ]

Father's Education

Number of years of school completed: [   ]

Highest diploma/degree:

- ☐ None, not currently in school
- ☐ None, but currently in diploma or degree-oriented program
- ☐ Vocational training (no high school diploma or GED)
- ☐ GED
- ☐ High school diploma
- ☐ Vocational training (post high school)
- ☐ Associates degree
- ☐ Bachelors degree
- ☐ Masters degree
- ☐ Doctoral degree
- ☐ Unable to obtain information

Unable to obtain information

- ☐ Refused
- ☐ Unknown by patient or family
- ☐ Discharged/expired before asked
- ☐ Other
- ☐ Other Reason

Mother's Education

Number of years of school completed: [   ]

Highest diploma/degree:

- ☐ None, not currently in school
- ☐ None, but currently in diploma or degree-oriented program
- ☐ Vocational training (no high school diploma or GED)
- ☐ GED
- ☐ High school diploma Vocational training (post high school)
- ☐ Associates degree
- ☐ Bachelors degree
- ☐ Masters degree
- ☐ Doctoral degree
- ☐ Unable to obtain information

Unable to obtain information

- ☐ Refused
- ☐ Unknown by patient or family
- ☐ Discharged/expired before asked
- ☐ Other

  Other Reason [   ]

Military Service

Subject on Active Duty?
- ○ Yes
- ○ No

Branch of service
- ☐ Army
- ☐ Air Force
- ☐ Marine corps
- ☐ Navy
- ☐ Army Reserve
- ☐ Air Force Reserve
- ☐ Navy Reserve
- ☐ Army National Guard
- ☐ Air National Guard

Rank
- ☐ Junior enlisted (lower than NCO)
- ☐ NCO* (non-commissioned officers)
- ☐ Officer (and senior warrant officers)

Military occupation
- ☐ Combat
- ☐ Non-combat

Deployment
- ☐ None
- ☐ Afghanistan
- ☐ Africa
- ☐ Germany
- ☐ Iraq
- ☐ Other

Other Deployment _____

Subject Notes/Informed Consent

Patient Number [   ]

Form Completion Status
- ☐ In Progress
- ☐ Complete
- ☐ Errors
- ☐ Due

Form Completion Note
[   ]

Age at time of Injury [   ]

Site
- ☐ UMC Brackenridge
- ☐ University of Pittsburgh
- ☐ Mount Sinai
- ☐ UCSF

Patient Category
- ⊙ ED Only
- ⊙ Hospital admit with ICU
- ⊙ Hospital admit no ICU
- ⊙ Rehab patient

Consent Source
- ☐ Patient
- ☐ Legal surrogate
- ☐ Parent
- ☐ Other family member
- ☐ Enrolled under approved waiver

Timing of Consent
- ☐ Written Informed Consent BEFORE Enrollment
- ☐ Written Informed Consent AFTER Enrollment

Timing of consent for pediatric patient
- ☐ Written assent BEFORE enrollment
- ☐ Written assent AFTER enrollment

Consented by:
- ☐ MD
- ☐ RN
- ☐ Research Assistant
- ☐ Other

Specify other consent: [   ]
Date and Time [   ]
Time Since Injury [   ]

Consent Withdrawn
☐ Consent Withdrawn
- Date and time [   ]
- Time Since Injury [   ]

Reason for Withdrawn Consent
[   ]

Consented for:
- ☐ Data
- ☐ Plasma
- ☐ DNA
- ☐ MRI
- ☐ Outcome Measures

Medical History

Patient Number _____

Form Completion Status

☐ In Progress

☐ Complete

☐ Errors

☐ Due

Form Completion note _____

010. Cardiovascular:

☐ 011. Congenital heart disease

☐ 012. Arrhythmia

☐ 013. Ischemic heart disease

☐ 014. Valvular heart disease

☐ 015. Hypertension

☐ 016. Thromboembolic

☐ 017. Peripheral vascular disease

☐ Other _____

020. Endocrine:

☐ 021. Thyroid disorder

☐ 022. IDDM (Type I)

☐ 023. NIDDM (Type II)

☐ 029. Other _____

030. Eye, Ear, Nose & Throat:

☐ 031. Sinusitis

☐ 032. Vision abnormality

☐ 033. Hearing deficit

☐ 039. Other _____

040. Gastrointestinal:

☐ 041. GERD

☐ 042. GI bleed

☐ 043. Inflammatory bowel disease

☐ 044. Diarrhea secondary to _____

☐ 049. Other _____

050. Hematologic:

☐ 051. Anemia

☐ 052. HIV positive

☐ 053. AIDS

☐ 054. Sickle cell disease

☐ 055. Coagulopathy

☐ 059. Other _____

060. Hepatic:

☐ 061. Insufficiency

☐ 062. Failure

☐ 063. Hepatitis

☐ 064. Cirrhosis

☐ 069. Other _____

070. Musculoskeletal:

☐ 071. Arthritis

☐ 072. Spasticity

☐ 073. Pressure ulcers

☐ 079. Other _____

Medical History (2)

080. Neurologic:
- ☐ Spinal cord injury
- ☐ Vertebral injury
- ☐ Cerebral vascular anomaly
- ☐ Tumor
- ☐ 081. Cerebrovascular Accident
- ☐ 082. Transient Ischemic Attacks
- ☐ 083. Seizures
- ☐ 083. Seizures-Febrile
- ☐ 083. Seizures-Posttraumatic
- ☐ 083. Seizures-Idiopathic
- ☐ 083. Seizures-Alcohol
- ☐ 084. Epilepsy: partial
- ☐ 085: Epilepsy: focal
- ☐ 086. Epilepsy: other
- ☐ 087. Headache (non migraine)
- ☐ 088. Migraine headaches
- ☐ 089. Previous TBI
- ☐ 899. Other _____

090. Oncologic:
- ☐ 091. Leukemia
- ☐ 092. Lymphoma
- ☐ 093. Breast Cancer
- ☐ 094. Prostate Cancer
- ☐ 095. Lung Cancer
- ☐ 096. GI Cancer
- ☐ 097. Kidney Cancer
- ☐ 098. Cancer (other)
- ☐ 099. Other _____

100. Pulmonary:
- ☐ 101. COPD
- ☐ 102. Asthma
- ☐ 103. Pneumonia
- ☐ 104. Tuberculosis
- ☐ 109.Other _____

110. Psychiatric:
- ☐ 111. Anxiety
- ☐ 112. Depression
- ☐ 113. Sleep disorder
- ☐ 114. Schizophrenia
- ☐ 115. Other psychiatric disorder
- ☐ 119. Other _____

120. Renal:
- ☐ 121. Insufficiency
- ☐ 122. Failure
- ☐ 123. Chronic UTI's
- ☐ 129. Other _____

130. Social history:
- ☐ 131. Tobacco use
- ☐ 132. Alcohol use
- ☐ 133. Drug use
- ☐ 139. Other _____

140. Developmental history:
- ☐ 141. Learning disabilities
- ☐ 142. Attention deficit/ hyperactivity disorder
- ☐ 143. Developmentally Delayed
- ☐ 144. Other developmental disorder
- ☐ 149. Other _____

Early & Late Presentation

Patient Number [_____]	Form Completion Status
Date & Time of Injury [_____]	☐ In Progress
Form Completion note [_____]	☐ Complete

EARLY PRESENTATION

Method of Arrival
- ○ Ambulance
- ○ Helicopter
- ○ Medical mobile team
- ○ Walk in or drop off
- ○ Other

Specify other method of arrival: [_____]

Hypotension in field?
- ○ Yes
- ○ No
- ○ Unknown

Hypoxia in field?
- ○ Yes
- ○ No
- ○ Unknown

Intubated in field?
- ○ Yes
- ○ No
- ○ Unknown

Prehospital GCS [_____]
- ☐ Prehospital GCS Unknown

Date & Time of Prehospital GCS [_____]

Time Since Injury (Prehospital GCS) [_____]

Presentation
- ○ Primary-Directly to Study Hospital
- ○ Secondary-To First Hospital, then to Study Hospital

Date & Time of arrival to First Hospital [_____]

Time Since Injury (Arrival First Hospital) [_____]

LATE PRESENTATION

Date and Time of Presentation [_____]

Time Since Injury (Late Presentation) [_____]

Reason for Presentation
- ○ Self referral with complaints
- ○ Self referral on advice significant other
- ○ Routine screening
- ○ Repatriation
- ○ Professional referral

If Professional referral, which:
- ○ GP
- ○ Hospital
- ○ Other caretaker

Initial medical care directly after injury

Hospitalization:
- ○ Yes
- ○ No

If no: Outpatient treatment:
- ○ None
- ○ Emergency Room
- ○ Doctor's Office
- ○ Sick Bay (military)
- ○ Other health care provider
- ○ Infirmary (if incarcerated)

Date & Time of arrival to Study Hospital [_____]

Time Since Injury (Arrival Study Hospital) [_____]

Cause of Injury

Patient Number ⬚

Form Completion Note ⬚

Form Completion Status
- ☐ In Progress
- ☐ Complete

Injury Type
- ☐ Closed
- ☐ Penetrating
- ☐ Blast

Intention
- ☐ Intentional
- ☐ Unintentional
- ☐ Undetermined

Motor vehicle traffic accidents
- ☐ 810 Motor vehicle vs. Train
- ☐ 811 Motor vehicle vs. motor vehicle re-entering road
- ☐ 812 Motor vehicle vs. motor vehicle on the road
- ☐ 813 Motor vehicle vs. non-motor vehicle
- ☐ 814 Motor vehicle vs. pedestrian
- ☐ 815 Motor vehicle vs. object on the road
- ☐ 816 Motor vehicle loss of control on the road
- ☐ 819 Motor vehicle traffic accident, general
- ☐ .0 Driver of motor vehicle
- ☐ .1 Passenger in motor vehicle
- ☐ .2 Driver of motorcycle
- ☐ .3 Passenger on motorcycle
- ☐ .4 Occupant of streetcar
- ☐ .5 Rider of animal or cart
- ☐ .6 Pedal cyclist
- ☐ .7 Pedestrian
- ☐ .9 Unspecified person
- ☐ .8 Other specified person
- Other Person ⬚

Falls (Accidental)
- ☐ 884 Fall from one level to another
- ☐ 885 Fall on same level from slip, trip, or stumble
- ☐ 886 Fall on same level from contact with person
- ☐ 888 Fall, general

Striking against or struck by person or object (Accidental)
- ☐ 917.0 In sports (tackles)
- ☐ 917.1 Caused by crowd, collective fear or panic
- ☐ 917.9 Other

Cutting and piercing instruments (Accidental)
- ☐ 920.0 Powered lawn mower
- ☐ 920.1 Other powered hand tools
- ☐ 920.2 Powered household appliances
- ☐ 920.3 Knives, swords, and daggers
- ☐ 920 Cutting and piercing, general
- ☐ 986 Undetermined if accidental or intentional

Cause of Injury (2)

Injury Purposely Inflicted by Other Persons

- [ ] 960.0 Unarmed fight or brawl
- [ ] 960.1 Rape
- [ ] 961 Assault by corrosive or caustic substance
- [ ] 965 Assault by firearms and explosives
- [ ] 966 Assault by cutting and piercing instruments
- [ ] 967 Child and adult battering/other maltreatment
- [ ] 968 Assault by other or unspecified means
- [ ] 968.0 Assault by fire
- [ ] 968.1 Assault by pushing from a high place
- [ ] 968.2 Assault by striking by blunt or thrown object
- [ ] 968.3 Assault by hot liquid
- [ ] 968.4 Assault by criminal neglect
- [ ] 968.5 Assault by transport vehicle
- [ ] 968.6 Assault by air gun
- [ ] 968.7 Assault by human bite
- [ ] 968.8 Assault by OTHER SPECIFIED means
- [ ] 968.9 Assault by UNSPECIFIED means

Other accidental causes of injury

- [ ] 807 Railway accident
- [ ] 821 Motor vehicle off-road non-traffic accident
- [ ] 825 Motor vehicle accident – not traffic related
- [ ] 829 Other vehicle accident
- [ ] 876 Misadventure during medical care
- [ ] 899 Accident caused by fire
- [ ] 900 Environmental – excessive heat
- [ ] 906 Injury caused by animal
- [ ] 910 Accidental drowning and submersion
- [ ] 913 Accidental mechanical suffocation
- [ ] 916 Struck accidentally by falling object
- [ ] 918 Accidentally caught in or between objects
- [ ] 919 Accident caused by machinery
- [ ] 924 Accident caused by hot or caustic liquids or gases
- [ ] 925 Accident caused by electrical current
- [ ] 928 Other environmental or accidental causes
- [ ] 929 Late effects of accidental injury

Cause of Injury (3)

Firearms, air guns, and explosives

- ☐ 922 Accident caused by firearm and air gun missile
- ☐ 923 Accident caused by explosive material
- ☐ 985 Unknown if accidental or intentional

Suicide and Self-Inflicted Injury

- ☐ 950 Poisoning by solid and liquid substances
- ☐ 953 Hanging, strangulation, suffocation
- ☐ 955 Firearms, air guns, and explosives
- ☐ 956 Cutting and piercing instrument
- ☐ 958 Other and unspecified means
- ☐ 959 Late effects of self-inflicted injury

Place of Injury

- ○ Street/highway
- ○ Home
- ○ Work/school
- ○ Recreational
- ○ Military deployment
- ○ Other
- ○ Unknown

Safety

Helmet Used

- ○ Yes
- ○ No
- ○ Not Applicable
- ○ Unknown

Airbag Deployed

- ○ Yes
- ○ No
- ○ Not Applicable
- ○ Unknown

Seatbelt Used

- ○ Yes
- ○ No
- ○ Not Applicable
- ○ Unknown

Injuries and Injury Severity

Patient Number				

Form Completion Status
- ☐ In Progress
- ☐ Complete

ISS Score

AIS Completion Note

Injury/Diagnosis				

Body Region

Head and Neck	☐	☐	☐	☐
Brain Injury	☐	☐	☐	☐
Cervical Spine	☐	☐	☐	☐
Thoracic Spine	☐	☐	☐	☐
Lumbar Spine	☐	☐	☐	☐
Face	☐	☐	☐	☐
Thorax/Chest	☐	☐	☐	☐
Abdomen/Pelvic Contents	☐	☐	☐	☐
Upper Extremities	☐	☐	☐	☐
Lower Extremities	☐	☐	☐	☐
Pelvic Girdle	☐	☐	☐	☐
Externa	☐	☐	☐	☐

AIS

1	☐	☐	☐	☐
2	☐	☐	☐	☐
3	☐	☐	☐	☐
4	☐	☐	☐	☐
5	☐	☐	☐	☐
6	☐	☐	☐	☐

ICD9

LOC PTA

Patient Number [_____] Form Completion Note [_____]	Form Completion Status ☐ In Progress ☐ Complete

Date and time LOC Assessment

[_____]

Time Since Injury (LOC Assessment)

[_____]

LOC Reported By
- ○ Patient
- ○ Relative/friend/caretaker

Loss Of Consciousness
- ○ No
- ○ Yes
- ○ Unknown

LOC Duration
- ○ None
- ○ <1 minute
- ○ 1-29 minutes
- ○ 30-59 minutes
- ○ 1-24 hours
- ○ >24 hours
- ○ >7 days
- ○ Unknown

LOC Lucid Interval
- ○ No
- ○ Yes

Time of assessment
(not necessary if Date and time is entered)
- ○ ED Discharge
- ○ ICU Discharge
- ○ Hospital Discharge

PTA (Post Traumatic Amnesia)
- ○ No
- ○ Yes
- ○ Suspected
- ○ Unknown

PTA Duration
- ○ None
- ○ <1 minute
- ○ 1-29 minutes
- ○ 30-59 minutes
- ○ 1-24 hours
- ○ >24 hours
- ○ >7 days
- ○ Unknown

Screening for Previous TBI

Patient Number		Form Completion Status
Form Completion Note		☐ In Progress
		☐ Complete

1. Have you ever been <u>hospitalized or treated in an emergency room</u> following an injury to your head or neck? Think about any childhood injuries you remember or were told about.
   - ○ Yes   ○ No

2. Have you ever injured your head or neck in a <u>car accident</u> or from some other moving vehicle accident, e.g., car, truck, bicycle, van, all terrain vehicle?
   - ○ Yes   ○ No

3. Have you ever injured your head or neck in a <u>fall or from being hit by something</u>? For example slipping on ice, a wet floor, the street, etc, or while walking. Falling from a curb, stairs, stair, roof, etc. Falling on a hard floor, ice, rocks, etc.
   - ○ Yes   ○ No

4. Have you ever injured your head or neck in <u>sports</u>, e.g., football, soccer, skiing, blading, boarding, basketball, baseball, biking, horse back riding?
   - ○ Yes   ○ No

5. Have you ever injured your head or neck in a <u>fight, assault, from being hit by someone</u> or being shaken violently?
   - ○ Yes   ○ No

6. Have you ever been nearby when <u>an explosion or a blast</u> occurred? If you served in the military, think about any combat-related incidents.
   - ○ Yes   ○ No

If all above are "no" then stop. If answered "yes" to any of the questions above, ask:

7. Were you <u>knocked out or unconscious</u> following any of the injuries you mentioned above?
   DO NOT INCLUDE LOSING CONSCIOUSNESS DUE TO DRUG OVERDOSE OR FROM BEING CHOKED (see #9, below).
   - ○ Yes   ○ No

Screening for Previous TBI (2)

If answer to #7 is "Yes", ask:

7A. How long were you knocked out or did you lose consciousness? (If identified multiple injuries with loss of consciousness, ask for each. If not sure of the time frame, encourage them to make their best guess.)

Injury #	1	2	3	4	5
How long were you knocked out?					
How old were you?					
If more than 5, how many more?					
Longest period of unconsciousness?					
How many ≥ 30 mins.?					
Youngest age?					

If answer to #7 is "No", ask:

8. Were you dazed, confused or do you or have a gap in your memory from the injury(ies) you mentioned above? [RULE OUT ALCOHOL BLACKOUTS]

　　　○ Yes　　　　　○ No

8A. How long were you dazed or confused? (If identified multiple injuries with period of confusion, ask for each. If not sure of the time frame, encourage them to make their best guess.)

Injury #	1	2	3	4	5
How long were you dazed &confused?					
How old were you?					
If more than 5, how many more?					
Longest period confused?					
How many ≥ 30 mins.?					
Youngest age?					

9. Have you ever lost consciousness from a drug overdose or being choked?

Number of times from a drug overdose [　　　]

Number of times from being choked [　　　]

Emergency Department

Patient Number	
Form Completion Note	

Form Completion Status
- ☐ In Progress
- ☐ Complete

Intubated in ED

   ○ Yes   ○ No

Note: [ ]

ED Arrival:

SBP	
DBP	
HR	
RR	

Ventilation
- ☐ Assisted ☐ Spontaneous

Temp, °C [ ]
SpO2 [ ]

ED Discharge:

SBP	
DBP	
HR	
RR	

Ventilation
- ☐ Assisted ☐ Spontaneous

Temp, °C [ ]
SpO2 [ ]

ED ARRIVAL GCS

ED Arrival GCS Assmt Complete
- ☐ COMPLETE
- ☐ NOT DONE
- ☐ NOT FOUND

Time of Assessment:
- ☐ ED Admission
- ☐ Post-Stabilization

Date & Time of GCS [ ]
Time Since Injury [ ]
Assessment Conditions
- ☐ Sedated
- ☐ Paralyzed
- ☐ No Sedation or Paralysis
- ☐ Other

Specify Other Assmt Condition [ ]

ED DISCHARGE GCS

ED Arrival GCS Assmt Complete
- ☐ COMPLETE
- ☐ NOT DONE
- ☐ NOT FOUND

Date & Time of GCS [ ]
Time Since Injury [ ]
Assessment Conditions
- ☐ Sedated
- ☐ Paralyzed
- ☐ No Sedation or Paralysis
- ☐ Other

Specify Other Assmt Condition [ ]

Emergency Department (2)

ED ARRIVAL GCS

Pupillary reactivity:
- ☐ Both pupils reactive
- ☐ One non-reacting pupil
- ☐ Both pupils non-reactive
- ☐ ED Arrival Pupils Not Done

Right Pupil Size
- ☐ 1 ☐ 2 ☐ 3 ☐ 4
- ☐ 5 ☐ 6 ☐ 7 ☐ 8

Rt Pupil Reactivity
- ☐ YES ☐ NO

Left Pupil Size
- ☐ 1 ☐ 2 ☐ 3 ☐ 4
- ☐ 5 ☐ 6 ☐ 7 ☐ 8

Lt Pupil Reactivity
- ☐ YES ☐ NO

ED DISCHARGE GCS

Pupillary reactivity:
- ☐ Both pupils reactive
- ☐ One non-reacting pupil
- ☐ Both pupils non-reactive
- ☐ ED Arrival Pupils Not Done

Right Pupil Size
- ☐ 1 ☐ 2 ☐ 3 ☐ 4
- ☐ 5 ☐ 6 ☐ 7 ☐ 8

Rt Pupil Reactivity
- ☐ YES ☐ NO

Left Pupil Size
- ☐ 1 ☐ 2 ☐ 3 ☐ 4
- ☐ 5 ☐ 6 ☐ 7 ☐ 8

Lt Pupil Reactivity
- ☐ YES ☐ NO

ED ARRIV GCS SCORE:

Eye Opening
- ☐ 1-No Response
- ☐ 2-To Pain
- ☐ 3-To Verbal Command
- ☐ 4-Spontaneously
- ☐ Eyes Untestable

Best Verbal Response
- ☐ 1-No Response
- ☐ 2-Incomprehensible Sounds
- ☐ 3-Inappropriate Words
- ☐ 4-Disoriented & Converses
- ☐ 5-Oriented & Converses
- ☐ Verbal Untestable

ED D/C GCS SCORE:

Eye Opening
- ☐ 1-No Response
- ☐ 2-To Pain
- ☐ 3-To Verbal Command
- ☐ 4-Spontaneously
- ☐ Eyes Untestable

Best Verbal Response
- ☐ 1-No Response
- ☐ 2-Incomprehensible Sounds
- ☐ 3-Inappropriate Words
- ☐ 4-Disoriented & Converses
- ☐ 5-Oriented & Converses
- ☐ Verbal Untestable

Emergency Department (3)

ED ARRIV GCS SCORE:

Best Motor Response
- ☐ 1-No Response
- ☐ 2-Extension
- ☐ 3-Flexion Abnormal
- ☐ 4-Flexion Withdrawal
- ☐ 5-Localizes to Pain
- ☐ 6-Obeys Commands

☐ Motor Untestable

GCS Total [　　　]

☐ 1 or more components untestable

ED D/C GCS SCORE:

Best Motor Response
- ☐ 1-No Response
- ☐ 2-Extension
- ☐ 3-Flexion Abnormal
- ☐ 4-Flexion Withdrawal
- ☐ 5-Localizes to Pain
- ☐ 6-Obeys Commands

☐ Motor Untestable

GCS Total [　　　]

☐ 1 or more components untestable

Labs

	Not Done	Results	Unit	Value in SI Units	
White blood cell	☐		X109/L or X103/μL		
Hemoglobin	☐		g/dL		mmol/L
Hematocrit	☐		%		
Platelet	☐		X109/L or X103/μL		
Osmolality	☐		mOsm/kg		
INR	☐				
PT	☐		Seconds		
aPTT	☐		Seconds		
Sodium	☐		mmol/L or mEq/L		
Potassium	☐		mmol/L or mEq/L		
Chloride	☐		mmol/L or mEq/L		
CO2	☐		mmol/L or mEq/L		
Glucose	☐		mg/dL		mmol/L
Creatine	☐		mg/dL		μmol/L
BUN	☐		mg/dL		mmol/L
Lactate	☐		mg/dL		mmol/L

Emergency Department (4)

Toxic Drug Screen

Type of sample
- ⊙ Serum ⊙ Urine

☐ Tox Screen Not Done

Results:

☐ None	☐ Opioids
☐ Benzodiazepines	☐ Cannabis
☐ Amphetamines	☐ Cocaine
☐ Barbiturates	☐ PCP
☐ Methadone	☐ Other

Blood Alcohol Done
- ⊙ Yes ⊙ No

Blood Alcohol Level
- [＿＿＿＿] mg/100ml blood

Pregnancy Test Done
- ⊙ Yes ⊙ No

Type of sample
- ⊙ Serum ⊙ Urine

Result:
- ⊙ Positive ⊙ Negative

IV fluids

☐ Crystalloids	☐ Hypertonic saline
☐ Blood	☐ Albumin
☐ Vasopressors	☐ Mannitol
☐ None	

First ABG

ED ABG Completion
- ⊙ Yes ⊙ No

pH [＿＿＿＿]
pCO2 mmHg [＿＿＿＿]
paO2 mmHg [＿＿＿＿]
HCO3 mmol/L or mEq/L [＿＿＿＿]
BE [＿＿＿＿]
BD [＿＿＿＿]
FiO2 [＿＿＿＿]

☐ FiO2 Unknown

Conditions:
- ☐ Preintubation, Room Air
- ☐ Preintubation O2
- ☐ Postintubation
- ☐ Unknown

Complicating Events

Aspiration
- ⊙ Yes ⊙ No ⊙ Unknown

Cardiopulmonary arrest
- ⊙ Yes ⊙ No

Seizures in ED
- ⊙ Yes ⊙ No

Hypotension (SBP < 90)
- ⊙ Yes ⊙ No

Hypoxia (SpO2 < 95)
- ⊙ Yes ⊙ No

Date & Time ED Discharge [＿＿＿＿]
Time Since Injury (ED discharge) [＿＿＿＿]

Destination
- ☐ Discharge home
- ☐ Transferred other facility
- ☐ Hospital admission--Ward
- ☐ Hospital admission--Stepdown Unit
- ☐ Hospital admission--ICU
- ☐ Hospital admission--Operating room
- ☐ Expired

Hospital Admission/Discharge

Patient Number [____]
Form Completion Status
   ☐ In Progress
   ☐ Complete
Hospital Completion Note
[____]

DNR Written Date Time [____]
Time Since Injury (DNR) [____]
Support Withdrawn/Comfort Care
Date Time [____]
Time Since Injury (Support Withdrawn) [____]

Date & Time of Admission	[____]	[____]	[____]	[____]
Time Since Injury (Ward Admis)	[____]	[____]	[____]	[____]
Previous Unit				
ED	☐	☐	☐	☐
OR	☐	☐	☐	☐
CT-Angio	☐	☐	☐	☐
Ward	☐	☐	☐	☐
Hospital transfer	☐	☐	☐	☐
ICU	☐	☐	☐	☐
Weight (kg)	[____]	[____]	[____]	[____]
Height (cm)	[____]	[____]	[____]	[____]
Date & Time of Discharge	[____]	[____]	[____]	[____]
Time Since Injury (Ward Disch)	[____]	[____]	[____]	[____]

Hospital Discharge Date Time
[____]

Time Since Injury (Hosp Discharge)
[____]

Discharge to:
  ☐ Other hospital
  ☐ Rehab unit
  ☐ Nursing home
  ☐ SNF
  ☐ Home
  ☐ Other
Discharge to Other [____]

Discharge Status
  ⚪ Alive
  ⚪ Dead
Death Date Time [____]
Time Since Injury (Death) [____]
Principle Cause of Death
  ☐ Head injury/initial injury
  ☐ Head injury/secondary
    intracranial damage
  ☐ Systemic trauma
  ☐ Medical complications
  ☐ Other
Death Cause Other [____]

Complications (1)

Patient Number [   ]

Form Completion Status
- ☐ In Progress
- ☐ Complete

Does patient have complications?
- ☐ Yes
- ☐ No

NEUROLOGICAL
- ☐ Rhinorrhea
- ☐ Otorrhea
- ☐ Meningitis
- ☐ Seizure
- ☐ Ventriculitis
- ☐ Stroke
- ☐ Neurogenic Shock
- ☐ Other CSF Leak
- ☐ Other [   ]
- ☐ Other [   ]

CARDIOVASCULAR
- ☐ Cardiac Arrest
- ☐ CHF
- ☐ DVT
- ☐ Major Arrhythmia
- ☐ MI
- ☐ Hypertension Requiring Treatment
- ☐ Hypotension Requiring Treatment
- ☐ Hemorrhagic Shock
- ☐ Other [   ]
- ☐ Other [   ]

HEMATOPOETIC
- ☐ Coagulopathy
- ☐ DIC
- ☐ Anemia Requiring Treatment
- ☐ Other [   ]
- ☐ Other [   ]

PULMONARY
- ☐ ARDS
- ☐ Fat Embolus
- ☐ Pulmonary Embolism
- ☐ Pleural Effusions
- ☐ Pneumonia
- ☐ Presumed Pneumonia
- ☐ Respiratory Failure
- ☐ VAP
- ☐ Asthma
- ☐ Other [   ]
- ☐ Other [   ]

GI/ABDOMEN
- ☐ Abdominal
- ☐ Compartment Syndrome
- ☐ Bowel Obstruction
- ☐ GI Bleed
- ☐ Hepatic Encephalopathy
- ☐ Hepatic Failure
- ☐ Pancreatitis
- ☐ Renal Failure
- ☐ Other [   ]
- ☐ Other [   ]

Complications (2)

WOUND
- ☐ Abcess
- ☐ Seroma /hematoma /bleeding
- ☐ Wound Dehiscence
- ☐ Wound Infection
- ☐ Pressure Ulcer
- ☐ Other [_____]
- ☐ Other [_____]

LAB ABNORMALITIES
- ☐ Hypoglycemia
- ☐ Hyperglycemia
- ☐ Hyponatremia
- ☐ Hypernatremia
- ☐ PT/PTT/INR Abnormality
- ☐ Other [_____]
- ☐ Other [_____]

INFECTION OTHER THAN PNEUMONIA / WOUND
- ☐ Bacteremia
- ☐ Fever (Temp>38.5) of unknown origin
- ☐ Presumed Infection
- ☐ Sepsis
- ☐ Septicemia
- ☐ UTI
- ☐ Septic Shock
- ☐ Other [_____]
- ☐ Other [_____]

OTHER COMPLICATIONS
- ☐ MSOF
- ☐ Transfusion Reaction

Surgeries

If more than 1 surgical procedure was performed during one surgery, please list each procedure on their own line.
The same start and end date/time will indicate that the procedures were performed during the same surgery.

ICD9 Code				
Date/Time Surgery Start				
Time Since Injury (Surgery Start)				
Date/Time Surgery End				
Time Since Injury (Surgery End)				
Surgery Timing				
Hypotension				
# times SBP < 90				
Hypoxia				
# times SpO2 < 95				

Monitoring Devices

Patient Number	☐	Form Completion Status

Patient Number [   ]

Form Completion Status
☐ In Progress
☐ Complete

Form Completion Note [   ]

ICP Monitor Used
○ Yes
○ No

ICP MONITORS

Unit

ED	○	○	○	○
OR	○	○	○	○
ICU	○	○	○	○

ICP Location

Right	○	○	○	○
Left	○	○	○	○

Device Used

Ventriculostomy	☐	☐	☐	☐
Subdural	☐	☐	☐	☐
Intraparenchymal	☐	☐	☐	☐
Epidural	☐	☐	☐	☐
Other	☐	☐	☐	☐

Other ICP Device	[ ]	[ ]	[ ]	[ ]
Date & Time ICP Inserted	[ ]	[ ]	[ ]	[ ]
Time Since Injury (ICP) Removed	[ ]	[ ]	[ ]	[ ]
Date & Time ICP Removed	[ ]	[ ]	[ ]	[ ]
Time Since Injury (ICP) Removed	[ ]	[ ]	[ ]	[ ]

Reason for Stopping

Monitor/catheter failure	☐	☐	☐	☐
Patient considered unsalvageable	☐	☐	☐	☐
Patient died	☐	☐	☐	☐
Clinically no longer required	☐	☐	☐	☐

Form Completion Status (1)

Patient Number		Date & Time of assessment	
TOTAL Time Used (minutes)		Time Since Injury	

CORE Time Used (minutes): _____

GOS-E Completion Status:
- ☐ In Progress
- ☐ Complete
- ☐ Not Complete

If Not Complete, Reason:
- ☐ Death
- ☐ Incarcerated
- ☐ Refusal
- ☐ Cognitively unable
- ☐ Physically unable
- ☐ Lost to follow up
- ☐ Not appropriate for patient
- ☐ Phone interview
- ☐ Reasons unrelated to the patient
- ☐ Other (describe)

If Other, Describe: _____

Neurological Assessment Completion Status:
- ☐ In Progress
- ☐ Complete
- ☐ Not Complete

If Not Complete, Reason:
- ☐ Death
- ☐ Incarcerated
- ☐ Refusal
- ☐ Cognitively unable
- ☐ Physically unable
- ☐ Lost to follow up
- ☐ Not appropriate for patient
- ☐ Phone interview
- ☐ Reasons unrelated to the patient
- ☐ Other (describe)

If Other, Describe: _____

Post Discharge Assessment
Completion Status:
- ☐ In Progress
- ☐ Complete
- ☐ Not Complete

If Not Complete, Reason:
- ☐ Death
- ☐ Incarcerated
- ☐ Refusal
- ☐ Cognitively unable
- ☐ Physically unable
- ☐ Lost to follow up
- ☐ Not appropriate for patient
- ☐ Phone interview
- ☐ Reasons unrelated to the patient
- ☐ Other (describe)

If Other, Describe: _____

GOS-E Pediatric Completion Status:
- ☐ In Progress
- ☐ Complete
- ☐ Not Complete

If Not Complete, Reason:
- ☐ Death
- ☐ Incarcerated
- ☐ Refusal
- ☐ Cognitively unable
- ☐ Physically unable
- ☐ Lost to follow up
- ☐ Not appropriate for patient
- ☐ Phone interview
- ☐ Reasons unrelated to the patient
- ☐ Other (describe)

If Other, Describe: _____

Form Completion Status (2)

EXTENDED Time Used (minutes):

PCL-C Completion Status:
- ☐ In Progress
- ☐ Complete
- ☐ Not Complete

If Not Complete, Reason:
- ☐ Death
- ☐ Incarcerated
- ☐ Refusal
- ☐ Cognitively unable
- ☐ Physically unable
- ☐ Lost to follow up
- ☐ Not appropriate for patient
- ☐ Phone interview
- ☐ Reasons unrelated to the patient
- ☐ Other (describe)

If Other, Describe:

SWLS Completion Status:
- ☐ In Progress
- ☐ Complete
- ☐ Not Complete

If Not Complete, Reason:
- ☐ Death
- ☐ Incarcerated
- ☐ Refusal
- ☐ Cognitively unable
- ☐ Physically unable
- ☐ Lost to follow up
- ☐ Not appropriate for patient
- ☐ Phone interview
- ☐ Reasons unrelated to the patient
- ☐ Other (describe)

If Other, Describe:

CHART-SF Completion Status:
- ☐ In Progress
- ☐ Complete
- ☐ Not Complete

If Not Complete, Reason:
- ☐ Death
- ☐ Incarcerated
- ☐ Refusal
- ☐ Cognitively unable
- ☐ Physically unable
- ☐ Lost to follow up
- ☐ Not appropriate for patient
- ☐ Phone interview
- ☐ Reasons unrelated to the patient
- ☐ Other (describe)

If Other, Describe:

BSI 18 Completion Status:
- ☐ In Progress
- ☐ Complete
- ☐ Not Complete

If Not Complete, Reason:
- ☐ Death
- ☐ Incarcerated
- ☐ Refusal
- ☐ Cognitively unable
- ☐ Physically unable
- ☐ Lost to follow up
- ☐ Not appropriate for patient
- ☐ Phone interview
- ☐ Reasons unrelated to the patient
- ☐ Other (describe)

If Other, Describe:

Form Completion Status (3)

RPQ Completion Status:
- ☐ In Progress
- ☐ Complete
- ☐ Not Complete

If Not Complete, Reason:
- ☐ Death
- ☐ Incarcerated
- ☐ Refusal
- ☐ Cognitively unable
- ☐ Physically unable
- ☐ Lost to follow up
- ☐ Not appropriate for patient
- ☐ Phone interview
- ☐ Reasons unrelated to the patient
- ☐ Other (describe)

If Other, Describe: [_____]

ADVANCED Time Used (minutes):
[_____]

TMT Completion Status:
- ☐ In Progress
- ☐ Complete
- ☐ Not Complete

If Not Complete, Reason:
- ☐ Death
- ☐ Incarcerated
- ☐ Refusal
- ☐ Cognitively unable
- ☐ Physically unable
- ☐ Lost to follow up
- ☐ Not appropriate for patient
- ☐ Phone interview
- ☐ Reasons unrelated to the patient
- ☐ Other (describe)

If Other, Describe: [_____]

WAIS IV Completion Status:
- ☐ In Progress
- ☐ Complete
- ☐ Not Complete

If Not Complete, Reason:
- ☐ Death
- ☐ Incarcerated
- ☐ Refusal
- ☐ Cognitively unable
- ☐ Physically unable
- ☐ Lost to follow up
- ☐ Not appropriate for patient
- ☐ Phone interview
- ☐ Reasons unrelated to the patient
- ☐ Other (describe)

If Other, Describe: [_____]

CVLT-II Completion Status:
- ☐ In Progress
- ☐ Complete
- ☐ Not Complete

If Not Complete, Reason:
- ☐ Death
- ☐ Incarcerated
- ☐ Refusal
- ☐ Cognitively unable
- ☐ Physically unable
- ☐ Lost to follow up
- ☐ Not appropriate for patient
- ☐ Phone interview
- ☐ Reasons unrelated to the patient
- ☐ Other (describe)

If Other, Describe: [_____]

Brief Symptom Inventory (1)

Patient Number [ ]	Form Completion Status
HOW MUCH WERE YOU DISTRESSED BY:	☐ In Progress ☐ Complete ☐ Not Complete

1. **Faintness or dizziness**
   - ☐ 0- Not at all
   - ☐ 1- A little bit
   - ☐ 2- Moderately
   - ☐ 3- Quite a bit
   - ☐ 4- Extremely

2. **Feeling no interest in things**
   - ☐ 0- Not at all
   - ☐ 1- A little bit
   - ☐ 2- Moderately
   - ☐ 3- Quite a bit
   - ☐ 4- Extremely

3. **Nervousness or shakiness inside**
   - ☐ 0- Not at all
   - ☐ 1- A little bit
   - ☐ 2- Moderately
   - ☐ 3- Quite a bit
   - ☐ 4- Extremely

4. **Pains in heart for chest**
   - ☐ 0- Not at all
   - ☐ 1- A little bit
   - ☐ 2- Moderately
   - ☐ 3- Quite a bit
   - ☐ 4- Extremely

5. **Feeling lonely**
   - ☐ 0- Not at all
   - ☐ 1- A little bit
   - ☐ 2- Moderately
   - ☐ 3- Quite a bit
   - ☐ 4- Extremely

6. **Feeling tense or keyed up**
   - ☐ 0- Not at all
   - ☐ 1- A little bit
   - ☐ 2- Moderately
   - ☐ 3- Quite a bit
   - ☐ 4- Extremely

7. **Nausea or upset stomach**
   - ☐ 0- Not at all
   - ☐ 1- A little bit
   - ☐ 2- Moderately
   - ☐ 3- Quite a bit
   - ☐ 4- Extremely

8. **Feeling blue**
   - ☐ 0- Not at all
   - ☐ 1- A little bit
   - ☐ 2- Moderately
   - ☐ 3- Quite a bit
   - ☐ 4- Extremely

9. **Suddenly scared for no reason**
   - ☐ 0- Not at all
   - ☐ 1- A little bit
   - ☐ 2- Moderately
   - ☐ 3- Quite a bit
   - ☐ 4- Extremely

10. **Trouble getting your breath**
    - ☐ 0- Not at all
    - ☐ 1- A little bit
    - ☐ 2- Moderately
    - ☐ 3- Quite a bit
    - ☐ 4- Extremely

Brief Symptom Inventory (2)

11. Feelings of worthlessness
- ☐ 0- Not at all
- ☐ 1- A little bit
- ☐ 2- Moderately
- ☐ 3- Quite a bit
- ☐ 4- Extremely

12. Spells or terror or panic
- ☐ 0- Not at all
- ☐ 1- A little bit
- ☐ 2- Moderately
- ☐ 3- Quite a bit
- ☐ 4- Extremely

13. Numbness or tingling in parts of your body
- ☐ 0- Not at all
- ☐ 1- A little bit
- ☐ 2- Moderately
- ☐ 3- Quite a bit
- ☐ 4- Extremely

14. Feeling hopeless about the future
- ☐ 0- Not at all
- ☐ 1- A little bit
- ☐ 2- Moderately
- ☐ 3- Quite a bit
- ☐ 4- Extremely

15. Feeling so restless you couldn't sit still
- ☐ 0- Not at all
- ☐ 1- A little bit
- ☐ 2- Moderately
- ☐ 3- Quite a bit
- ☐ 4- Extremely

16. Feeling weak in parts of your body
- ☐ 0- Not at all
- ☐ 1- A little bit
- ☐ 2- Moderately
- ☐ 3- Quite a bit
- ☐ 4- Extremely

17. Thoughts of ending your life
- ☐ 0- Not at all
- ☐ 1- A little bit
- ☐ 2- Moderately
- ☐ 3- Quite a bit
- ☐ 4- Extremely

18. Feeling fearful
- ☐ 0- Not at all
- ☐ 1- A little bit
- ☐ 2- Moderately
- ☐ 3- Quite a bit
- ☐ 4- Extremely

Raw Score		T Score	
Somatization		Somatization	
Depression		Depression	
Anxiety		Anxiety	
GSI		GSI	

Civilian PTSD Check List (1)

Patient Number [ ]

Below is a list of problems and complaints that veterans sometimes have in response to stressful life experiences. Please read each one carefully, and indicate how much you have been bothered by that problem in the last month.

Form Completion Status
☐ In Progress
☐ Complete
☐ Not Complete

1. Repeated, disturbing *memories, thoughts, or images* of a stressful experience from the past?
   ☐ 1- Not at all   ☐ 2- A little bit   ☐ 3- Moderately
   ☐ 4- Quite a bit   ☐ 5- Extremely

2. Repeated, disturbing *dreams* of a stressful experience from the past?
   ☐ 1- Not at all   ☐ 2- A little bit   ☐ 3- Moderately
   ☐ 4- Quite a bit   ☐ 5- Extremely

3. Suddenly *acting or feeling* as if a stressful experience *were happening* again (as if you were reliving it)?
   ☐ 1- Not at all   ☐ 2- A little bit   ☐ 3- Moderately
   ☐ 4- Quite a bit   ☐ 5- Extremely

4. Feeling *very upset* when *something reminded* you of a stressful experience from the past?
   ☐ 1- Not at all   ☐ 2- A little bit   ☐ 3- Moderately
   ☐ 4- Quite a bit   ☐ 5- Extremely

5. Having *physical reactions* (e.g., heart pounding, trouble breathing, or sweating) when something reminded you of a stressful experience from the past?
   ☐ 1- Not at all   ☐ 2- A little bit   ☐ 3- Moderately
   ☐ 4- Quite a bit   ☐ 5- Extremely

6. Avoid *thinking about or talking about* a stressful experience from the past or avoid having feelings related to it?
   ☐ 1- Not at all   ☐ 2- A little bit   ☐ 3- Moderately
   ☐ 4- Quite a bit   ☐ 5- Extremely

7. Avoid activities or situations because they remind you of a stressful experience from the past?
   ☐ 1- Not at all   ☐ 2- A little bit   ☐ 3- Moderately
   ☐ 4- Quite a bit   ☐ 5- Extremely

8. Trouble *remembering important parts* of a stressful experience from the past?
   ☐ 1- Not at all   ☐ 2- A little bit   ☐ 3- Moderately
   ☐ 4- Quite a bit   ☐ 5- Extremely

Civilian PTSD Check List (2)

9. *Loss of interest in things that you used to enjoy?*
   - ☐ 1- Not at all
   - ☐ 2- A little bit
   - ☐ 3- Moderately
   - ☐ 4- Quite a bit
   - ☐ 5- Extremely

10. *Feeling distant or cut off from other people?*
    - ☐ 1- Not at all
    - ☐ 2- A little bit
    - ☐ 3- Moderately
    - ☐ 4- Quite a bit
    - ☐ 5- Extremely

11. *Feeling emotionally numb or being unable to have loving feelings for those close to you?*
    - ☐ 1- Not at all
    - ☐ 2- A little bit
    - ☐ 3- Moderately
    - ☐ 4- Quite a bit
    - ☐ 5- Extremely

12. *Feeling as if your future will somehow be cut short?*
    - ☐ 1- Not at all
    - ☐ 2- A little bit
    - ☐ 3- Moderately
    - ☐ 4- Quite a bit
    - ☐ 5- Extremely

13. *Trouble falling or staying asleep?*
    - ☐ 1- Not at all
    - ☐ 2- A little bit
    - ☐ 3- Moderately
    - ☐ 4- Quite a bit
    - ☐ 5- Extremely

14. *Feeling irritable or having angry outbursts?*
    - ☐ 1- Not at all
    - ☐ 2- A little bit
    - ☐ 3- Moderately
    - ☐ 4- Quite a bit
    - ☐ 5- Extremely

15. *Having difficulty concentrating?*
    - ☐ 1- Not at all
    - ☐ 2- A little bit
    - ☐ 3- Moderately
    - ☐ 4- Quite a bit
    - ☐ 5- Extremely

16. *Being super alert or watchful on guard?*
    - ☐ 1- Not at all
    - ☐ 2- A little bit
    - ☐ 3- Moderately
    - ☐ 4- Quite a bit
    - ☐ 5- Extremely

17. *Feeling jumpy or easily startled?*
    - ☐ 1- Not at all
    - ☐ 2- A little bit
    - ☐ 3- Moderately
    - ☐ 4- Quite a bit
    - ☐ 5- Extremely

Total Score [_____]

18. Was the stressful experience the index head trauma that caused you to be seen at the study hospital or was it a different experience?
    - ☐ Head Trauma
    - ☐ Different Exp
    - ☐ Both

19. If different experience from question 18, how long ago did the stressful experience occur?
    [_____] ☐ weeks ☐ months ☐ years

CVLT

Patient Number	☐ In Progress
	☐ Complete
	☐ Not Complete

Form Completion Status

	Raw Score	Standard Score
Trial 1 Free Recall Correct		
Trial 2 Free Recall Correct		
Trial 3 Free Recall Correct		
Trial 4 Free Recall Correct		
Trial 5 Free Recall Correct		
Trial 1-5 Free Recall Correct		
List B Free Recall Correct		
Short Delay Free Recall Correct		
Short Delay Cued Recall Correct		
Long Delay Free Recall Correct		
Long Delay Cued Recall Correct		
Free-Recall Intrusions		
Cued-Recall Intrusions		
Total Intrusions		
Total Repetitions		
Long-Delay Yes/No RecognitionHits		
Total Recognition Discriminability		

CHART-SF (1)

Patient Number	Form Completion Status
	☐ In Progress
	☐ Complete
	☐ Not Complete

1. How many hours in a typical 24-hour day do you have someone with you to provide physical assistance for personal care activities such as eating, bathing, dressing, toileting and mobility?

Hours Paid Assistance [ ]   Hours unpaid (family, others) [ ]

2. How much time is someone with you in your home to assist you with activities that require remembering, decision making, or judgment?
   - ☐ Someone else is always with me to observe or supervise
   - ☐ Someone else is always around, but they only check on me now and then
   - ☐ Sometimes I am left alone for an hour or two
   - ☐ Sometimes I am left alone for most of the day
   - ☐ I have been left alone all day and all night, but someone checks in on me
   - ☐ I am left alone without anyone checking on me

3. How much of the time is someone with you to help you with remembering, decision making, or judgment when you go away from your home?
   - ☐ I am restricted from leaving, even with someone else
   - ☐ Someone is always with me to help with remembering, decision making, or judgment when I go anywhere
   - ☐ I go to places on my own as long as they are familiar
   - ☐ I do not need help going anywhere

4. On a typical day, how many hours are you out of bed? [ ]

5. In a typical week, how many days do you get out of your house and go somewhere? [ ]

6. In the last year, how many nights have you spent away from your home (excluding hospitalizations)?
   - ☐ None
   - ☐ 1-2
   - ☐ 3-4
   - ☐ 5 or more

CHART-SF (2)

7. How many hours per week do you spend working in a job for which you get paid? [_____] Occupation: [_____]
8. How many hours per week do you spend in school working toward a degree or in an accredited technical training program (including hours in class and studying)? [_____]
9. How many hours per week do you spend in active homemaking including parenting, housekeeping, and food preparation? [_____]
10. How many hours per week do you spend in home maintenance activities such as gardening, house repairs or home improvement? [_____]
11. How many hours per week do you spend in recreational activities such as sports, exercise, playing cards, or going to movies? Please do not include time spent watching TV or listening to the radio [_____]

12. How many other people do you live with? [_____]
13. Is one of them your spouse or significant other?
    ☐ Yes
    ☐ No
    ☐ N/A (lives alone)
14. Of the people you live with, how many are relatives (not including your spouse)? [_____]
15. How many business or organizational associates do you visit, phone, or write to at least once a month? [_____]
16. How many friends (non-relatives contacted outside business or organizational settings) do you visit, phone, or write to at least once a month? [_____]
17. With how many strangers have you initiated a conversation in the last month (for example, to ask information or place an order)?
    ☐ None
    ☐ 1-2
    ☐ 3-5
    ☐ 6 or more

CHART-SF (3)

18. Approximately what was the combined annual income, in the last year, of all family members in your household?
- ○ a. Less than 25,000 - If no ask e; if yes ask b
- ○ b. Less than 20,000 - If no select a; if yes ask c
- ○ c. Less than 15,000 - If no select b; if yes ask d
- ○ d. Less than 10,000 - If no select c; if yes select d
- ○ e. Less than 35,000 - If no ask f; if yes select e
- ○ f. Less than 50,000 - If no ask g; if yes select f
- ○ g. Less than 75,000 - If no select h; if yes select g
- ○ h. 75,000 or more

19. Approximately how much did you pay last year for medical care expenses?
- ○ Less than 1000
- ○ Less than 2500
- ○ Less than 5000
- ○ Less than 10000
- ○ 10000 or more

Scoring

Physical Total	
Cognitive Total	
Mobility Total	
Occupation Total	
Social Integration Total	
Self Sufficient Total	

Extended Glasgow Outcome Scale (1)

Patient Number

Respondent:
- ☐ Patient alone
- ☐ Relative/friend/caretaker alone
- ☐ Patient plus relative/friend/caretaker

Form Completion Status
- ☐ In Progress
- ☐ Complete
- ☐ Not Complete

Consciousness:

1. Is the head-injured person able to obey simple commands or say any words?
   - ☐ No (VS)   ☐ Yes

Independence at home:

2a. Is the assistance of another person at home essential every day for some activities of daily living?
   - ☐ No   ☐ Yes

2b. Do they need frequent help of someone to be around at home most of the time?
   - ☐ No (Upper SD)   ☐ Yes (Lower SD)

2c. Was assistance at home essential before the injury?
   - ☐ No   ☐ Yes

Independence outside home:

3a. Are they able to shop without assistance?
   - ☐ No (Upper SD)   ☐ Yes

3b. Were they able to shop without assistance before?
   - ☐ No   ☐ Yes

4a. Are they able to travel locally without assistance?
   - ☐ No (Upper SD)   ☐ Yes

4b. Were they able to travel locally without assistance before the injury?
   - ☐ No   ☐ Yes

Work:

5a. Are they currently able to work (or look after others at home) to their previous capacity?
   - ☐ No   ☐ Yes

5b. How restricted are they?
   - ☐ Reduced work capacity (Upper MD)
   - ☐ Able to work only in a sheltered workshop or non-competitive job or currently unable to work (Lower MD)

5c. Were they either working or seeking employment before the injury (answer 'yes') or were they doing neither (answer 'no')?
   - ☐ No   ☐ Yes

Extended Glasgow Outcome Scale (2)

Social and Leisure activities:

6a. Are they able to resume regular social and leisure activities outside home?

☐ No   ☐ Yes

6b. What is the extent of restriction on their social and leisure activities?

☐ Participate a bit less; at least half as often as before injury (Lower GR)

☐ Participate much less; less than half as often (Upper MD)

☐ Unable to participate; rarely, if ever, take part (Lower MD)

6c. Did they engage in regular social and leisure activities outside home before the injury?   ☐ No   ☐ Yes

Family and friendships:

7a. Has there been family or friendship disruption due to psychological problems?

☐ No   ☐ Yes

7b. What has been the extent of disruption or strain?

☐ Occasional - less than weekly (Lower GR)

☐ Frequent - once a week or more, but not tolerable (Upper MD)

☐ Constant - daily and intolerable (Lower MD)

7c. Were there problems with family or friends before the injury?

☐ No   ☐ Yes

Return to normal life:

8a. Are there any other current problems relating to the injury which affect daily life?   ☐ No (upper GR)   ☐ Yes (Lower GR)

8b. Were similar problems present before the injury?

☐ No   ☐ Yes

Epilepsy:

Since the injury has the head injured person had any epileptic fits?

☐ No   ☐ Yes

Have they been told that they are currently at risk of developing epilepsy?   ☐ No   ☐ Yes

Outcome

What is the most important factor in outcome?

☐ Effects of head injury

☐ Effects of illness or injury to another part of the body

☐ A mixture of these

Scoring: The patient's overall rating is based on the lowest outcome category indicated on the scale. Refer to Guidelines for further information concerning administration and scoring

GOSE Score

☐ 1-Dead

☐ 2-Vegetative State (VS)

☐ 3-Lower Severe Disability (Lower SD)

☐ 4-Upper Severe Disability (Upper SD)

☐ 5-Lower Moderate Disability (Lower MD)

☐ 6-Upper Moderate Disability (Upper MD)

☐ 7-Lower Good Recovery (Lower GR)

☐ 8-Upper Good Recovery (Upper GR)

Extended Glasgow Outcome Scale Pediatric

Patient Number [_____]

Respondent:
- ○ Patient alone
- ○ Relative/friend/caretaker alone
- ○ Patient plus relative/friend/caretaker

Form Completion Status
- ☐ In Progress
- ☐ Complete
- ☐ Not Complete

Consciousness:

1a. Is the head-injured person able to obey simple commands or say any words? OR Can he or she act/react/interact beyond reflexes?

☐ Yes ☐ No (VS)

Independence at home:

2a. Is the assistance of another person at home essential every day for some activities of daily living? OR Is the child dependent upon a caretaker more so than is expected based on age?

☐ Yes ☐ No

2b. Does the child need frequent help or for someone to be around at home most of the time? OR Does the child need frequent help from a caretaker to accomplish tasks that a child this age should be able to accomplish

☐ Yes (Lower SD) ☐ No (Upper SD)

Independence outside home:

3a. Is the child able to shop and travel without assistance? OR Does the child behave age appropriately outside the home?

☐ Yes ☐ No (Upper SD)

School/Work:

4a. Can the child function at work or in school at his or her previous capacity?

☐ Yes ☐ No

4b. Level of restriction:

i) Able to work only in a sheltered workshop or non-competitive job, in a school setting for severely impaired children or tutored at home, or currently unable to work or go to school.

☐ Yes (Lower MD) ☐ No

ii) Reduced work or school capacity.

☐ Yes (Upper MD) ☐ No

Extended Glasgow Outcome Scale Pediatric (2)

Social and Leisure activities:

5a. Is the child able to resume regular social and leisure activities?

☐ Yes   ☐ No

5b. What is the extent of restrictions on social and leisure activities?

☐ Participate a bit less; at least half as often as before injury (Lower GR)

☐ Participate much less; less than half as often (Upper MD)

☐ Unable to participate; rarely, if ever, take part (Lower MD)

Family and friendships:

6a. Are there psychological problems that have resulted in ongoing disruption with respect to either family or friendships?

☐ Yes   ☐ No

6b. What is the extent of disruption or strain?

☐ Occasional - less than weekly (Lower GR)

☐ Frequent - once a week or more, but not tolerable (Upper MD)

☐ Constant - daily and intolerable (Lower MD)

Return to normal life:

7a. Are there any other problems relating to the injury that affect daily life?

☐ Yes (Lower GR)   ☐ No (Upper GR)

Scoring: The patient's overall rating is based on the lowest outcome category indicated on the scale. Refer to Guidelines for further information concerning administration and scoring

GOSE Score

☐ 8-Dead

☐ 7-Vegetative State (VS)

☐ 6-Lower Severe Disability (Lower SD)

☐ 5-Upper Severe Disability (Upper SD)

☐ 4-Lower Moderate Disability (Lower MD)

☐ 3-Upper Moderate Disability (Upper MD)

☐ 2-Lower Good Recovery (Lower GR)

☐ 1-Upper Good Recovery (Upper GR)

Functional Independence Measure (1)

Patient Number [ ]	Form Completion Status ☐ In Progress ☐ Complete ☐ Not Complete

Motor Functions

Eating
☐ Complete independence
☐ Modified independence
☐ Supervision
☐ Minimal assistance (client 75%+)
☐ Moderate assistance (client 50%+)
☐ Maximal assistance (client 25%+)
☐ Total assistance (client 0%+)
☐ Not done at all

Dressing- upper body
☐ Complete independence
☐ Modified independence
☐ Supervision
☐ Minimal assistance (client 75%+)
☐ Moderate assistance (client 50%+)
☐ Maximal assistance (client 25%+)
☐ Total assistance (client 0%+)
☐ Not done at all

Grooming
☐ Complete independence
☐ Modified independence
☐ Supervision
☐ Minimal assistance (client 75%+)
☐ Moderate assistance (client 50%+)
☐ Maximal assistance (client 25%+)
☐ Total assistance (client 0%+)
☐ Not done at all

Dressing- lower body
☐ Complete independence
☐ Modified independence
☐ Supervision
☐ Minimal assistance (client 75%+)
☐ Moderate assistance (client 50%+)
☐ Maximal assistance (client 25%+)
☐ Total assistance (client 0%+)
☐ Not done at all

Bathing
☐ Complete independence
☐ Modified independence
☐ Supervision
☐ Minimal assistance (client 75%+)
☐ Moderate assistance (client 50%+)
☐ Maximal assistance (client 25%+)
☐ Total assistance (client 0%+)
☐ Not done at all

Toileting
☐ Complete independence
☐ Modified independence
☐ Supervision
☐ Minimal assistance (client 75%+)
☐ Moderate assistance (client 50%+)
☐ Maximal assistance (client 25%+)
☐ Total assistance (client 0%+)
☐ Not done at all

Functional Independence Measure (2)

Bladder management
- ☐ Complete independence
- ☐ Modified independence
- ☐ Supervision
- ☐ Minimal assistance (client 75%+)
- ☐ Moderate assistance (client 50%+)
- ☐ Maximal assistance (client 25%+)
- ☐ Total assistance (client 0%+)
- ☐ Not done at all

Bowel Management
- ☐ Complete independence
- ☐ Modified independence
- ☐ Supervision
- ☐ Minimal assistance (client 75%+)
- ☐ Moderate assistance (client 50%+)
- ☐ Maximal assistance (client 25%+)
- ☐ Total assistance (client 0%+)
- ☐ Not done at all

Bed, chair, wheelchair
- ☐ Complete independence
- ☐ Modified independence
- ☐ Supervision
- ☐ Minimal assistance (client 75%+)
- ☐ Moderate assistance (client 50%+)
- ☐ Maximal assistance (client 25%+)
- ☐ Total assistance (client 0%+)
- ☐ Not done at all

Toilet
- ☐ Complete independence
- ☐ Modified independence
- ☐ Supervision
- ☐ Minimal assistance (client 75%+)
- ☐ Moderate assistance (client 50%+)
- ☐ Maximal assistance (client 25%+)
- ☐ Total assistance (client 0%+)
- ☐ Not done at all

Tub, shower
- ☐ Complete independence
- ☐ Modified independence
- ☐ Supervision
- ☐ Minimal assistance (client 75%+)
- ☐ Moderate assistance (client 50%+)
- ☐ Maximal assistance (client 25%+)
- ☐ Total assistance (client 0%+)
- ☐ Not done at all

Walk
- ☐ Complete independence
- ☐ Modified independence
- ☐ Supervision
- ☐ Minimal assistance (client 75%+)
- ☐ Moderate assistance (client 50%+)
- ☐ Maximal assistance (client 25%+)
- ☐ Total assistance (client 0%+)
- ☐ Not done at all

Functional Independence Measure (3)

Stairs
- ☐ Complete independence
- ☐ Modified independence
- ☐ Supervision
- ☐ Minimal assistance (client 75%+)
- ☐ Moderate assistance (client 50%+)
- ☐ Maximal assistance (client 25%+)
- ☐ Total assistance (client 0%+)
- ☐ Not done at all

Cognitive Functions

Comprehension (auditory)
- ☐ Complete independence
- ☐ Modified independence
- ☐ Supervision
- ☐ Minimal assistance (client 75%+)
- ☐ Moderate assistance (client 50%+)
- ☐ Maximal assistance (client 25%+)
- ☐ Total assistance (client 0%+)
- ☐ Not done at all

Expression (verbal)
- ☐ Complete independence
- ☐ Modified independence
- ☐ Supervision
- ☐ Minimal assistance (client 75%+)
- ☐ Moderate assistance (client 50%+)
- ☐ Maximal assistance (client 25%+)
- ☐ Total assistance (client 0%+)
- ☐ Not done at all

Social interaction
- ☐ Complete independence
- ☐ Modified independence
- ☐ Supervision
- ☐ Minimal assistance (client 75%+)
- ☐ Moderate assistance (client 50%+)
- ☐ Maximal assistance (client 25%+)
- ☐ Total assistance (client 0%+)
- ☐ Not done at all

Problem solving
- ☐ Complete independence
- ☐ Modified independence
- ☐ Supervision
- ☐ Minimal assistance (client 75%+)
- ☐ Moderate assistance (client 50%+)
- ☐ Maximal assistance (client 25%+)
- ☐ Total assistance (client 0%+)
- ☐ Not done at all

Memory
- ☐ Complete independence
- ☐ Modified independence
- ☐ Supervision
- ☐ Minimal assistance (client 75%+)
- ☐ Moderate assistance (client 50%+)
- ☐ Maximal assistance (client 25%+)
- ☐ Total assistance (client 0%+)
- ☐ Not done at all

Neurological Assessment

Patient Number	[ ]
Date & Time of assessment	[ ]
Time Since Injury	[ ]
Completion Note	[ ]

Form Completion Status
☐ In Progress
☐ Complete
☐ Not Complete

Physical

Headache
○ Yes   ○ No

Nausea
○ Yes   ○ No

Vomiting
○ Yes   ○ No

Balance Problems
○ Yes   ○ No

Dizziness
○ Yes   ○ No

Visual Problems
○ Yes   ○ No

Fatigue
○ Yes   ○ No

Sensitivity to Light
○ Yes   ○ No

Sensitivity to Noise
○ Yes   ○ No

Numbness/Tingling
○ Yes   ○ No

Sleep

Drowsiness
○ Yes   ○ No

Sleeping less than usual
○ Yes   ○ No

Sleeping more than usual
○ Yes   ○ No

Trouble falling asleep
○ Yes   ○ No

Cognitive

Feeling mentally foggy
○ Yes   ○ No

Feeling slowed down
○ Yes   ○ No

Difficulty concentrating
○ Yes   ○ No

Difficulty remembering
○ Yes   ○ No

Emotional

Irritability
○ Yes   ○ No

Sadness
○ Yes   ○ No

More emotional
○ Yes   ○ No

Nervousness
○ Yes   ○ No

Do these symptoms worsen with:

Physical activity
○ Yes   ○ No

Cognitive activity
○ Yes   ○ No

Overall rating: How different is the person acting compared to his/her usual self?
○ 1 - Normal
○ 2
○ 3
○ 4
○ 5
○ 6 – Very Different

Post Discharge & Outpatient Care (1)

Patient Number _____
Date & Time of assessment _____
Time Since Injury _____
Completion Note _____

Form Completion Status
- ☐ In Progress
- ☐ Complete
- ☐ Not Complete

Post Disch

Patient Outcome
- ○ Alive   ○ Dead

Date of Death _____

Cause of Death
- ☐ Head injury/initial injury
- ☐ Head injury/secondary intracranial damage
- ☐ Systemic trauma
- ☐ Medical complications
- ☐ Other

Other Cause Of Death _____

Patient Residence
- ○ On date of assessment
- ○ On date of death

Residence
- ○ Home
- ○ Hospital
- ○ Rehab center
- ○ Nursing home
- ○ Other

Other Residence _____

Return to work/school
- ○ No
- ○ Sheltered
- ○ Partial
- ○ Full
- ○ N/A
- ○ Unknown

Family Strain/disruption
- ○ None
- ○ Minor
- ○ Moderate
- ○ Severe

Effect on marriage
- ○ None
- ○ Separated
- ○ Divorced
- ○ N/A

Is the patient currently involved with any legal issues resulting from the injuries incurred from the original incident?
- ○ Yes
- ○ No
- ○ Don't Know

Rehabilitation
- ○ None
- ○ Only as outpatient
- ○ General rehab (inpt)
- ○ TBI rehabilitation unit (inpt)
- ○ General long-term care unit (inpt)
- ○ Geriatric rehab unit (inpt)

If treated as an inpatient:
Admit date _____
Discharge date _____

Post Discharge & Outpatient Care (2)

Short term rehab interruptions

Interruption	1	2	3
Start Date			
End Date			

Reason

	1	2	3
Readmit to hospital	☐	☐	☐
Readmit to ICU	☐	☐	☐
Required surgical procedure	☐	☐	☐
Return to Work	☐	☐	☐
Other	☐	☐	☐
Other Reason			

Outpatient Therapy

If treated as an outpatient:

Start Date _____

Active Rehab Ongoing

○ Yes   ○ No

End Date _____

Frequency of outpatient therapy

○ Only follow-up; no active treatment
○ Less than once per week
○ Weekly
○ 2-3 times per week
○ Daily

Did the patient have any type(s) of outpatient therapy at all since discharge from the hospital?

○ Yes   ○ No

Type of Outpatient Therapy

☐ Physical therapy
☐ Occupational therapy
☐ Speech therapy
☐ Therapeutic recreation
☐ Cognitive remediation
☐ Vocational services
☐ Psychological services
☐ Nursing services
☐ Comprehensive day treatment
☐ Peer mentoring
☐ Social work/Case management
☐ Independent living training
☐ Home health
☐ Other hospital unit

Other _____

Rivermead Post-concussion Symptoms Questionnaire (1)

Patient Number _____

After a head injury or accident some people experience symptoms that can cause worry or nuisance. We would like to know if you now suffer any of the symptoms given below. Because many of these symptoms occur normally, we would like you to compare yourself now with before the accident. For each symptom listed below please select the number that most closely represents your answer.

Compared with **before** the accident, do you **now** (i.e., over the last 24 hours) suffer from:

Headaches
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

Feelings of dizziness
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

Nausea and/or vomiting
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

Noise sensitivity (easily upset by loud noise)
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

Sleep disturbance
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

Fatigue, tiring more easily
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

Being irritable, easily angered
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

Feeling depressed or tearful
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

Rivermead Post-concussion Symptoms Questionnaire (2)

Feeling frustrated or impatient
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

Forgetfulness, poor memory
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

Poor concentration
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

Taking longer to think
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

Blurred vision
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

RPQ-3 [   ]
RPQ-13 [   ]

Light sensitivity (easily upset by bright light)
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

Double vision
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

Restlessness
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

Are you experiencing any other difficulties? Please specify, and rate as above.

1. [   ]
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

2. [   ]
- ☐ 0-Not experienced at all
- ☐ 1- No more of a problem
- ☐ 2- A mild problem
- ☐ 3- A moderate problem
- ☐ 4- A severe problem

Satisfaction with Life Scale

Patient Number [＿＿＿＿＿]

DIRECTIONS: Below are five statements with which you may agree or disagree. Using the 1-7 scale, indicate your agreement with each item by selecting the appropriate number for that item. Please be open and honest in your responses.

Form Completion Status
- ☐ In Progress
- ☐ Complete
- ☐ Not Complete

1. In most ways my life is close to my ideal.
- ☐ 1- Strongly Disagree
- ☐ 2- Disagree
- ☐ 3- Slightly Disagree
- ☐ 4- Neither Agree nor Disagree
- ☐ 5- Slightly Agree
- ☐ 6- Agree
- ☐ 7- Strongly Agree

2. The conditions of my life are excellent.
- ☐ 1- Strongly Disagree
- ☐ 2- Disagree
- ☐ 3- Slightly Disagree
- ☐ 4- Neither Agree nor Disagree
- ☐ 5- Slightly Agree
- ☐ 6- Agree
- ☐ 7- Strongly Agree

3. I am satisfied with my life.
- ☐ 1- Strongly Disagree
- ☐ 2- Disagree
- ☐ 3- Slightly Disagree
- ☐ 4- Neither Agree nor Disagree
- ☐ 5- Slightly Agree
- ☐ 6- Agree
- ☐ 7- Strongly Agree

4. So far I have gotten the important things I want in life.
- ☐ 1- Strongly Disagree
- ☐ 2- Disagree
- ☐ 3- Slightly Disagree
- ☐ 4- Neither Agree nor Disagree
- ☐ 5- Slightly Agree
- ☐ 6- Agree
- ☐ 7- Strongly Agree

5. If I could live my life over, I would change almost nothing.
- ☐ 1- Strongly Disagree
- ☐ 2- Disagree
- ☐ 3- Slightly Disagree
- ☐ 4- Neither Agree nor Disagree
- ☐ 5- Slightly Agree
- ☐ 6- Agree
- ☐ 7- Strongly Agree

SWLS Total Score [＿＿＿＿＿]

Trail Making Test and WAIS IV

Patient Number	

Form Completion Status	Form Completion Status
☐ In Progress	☐ In Progress
☐ Complete	☐ Complete
☐ Not Complete	☐ Not Complete
Date	Date
Administered by:	Administered by:

TRAIL MAKING TEST (TMT)

Trail Making Part A
Time (in secs):
# of Errors:

Trail Making Part B
Time (in secs):
# of Errors:

WAIS IV
Age at Time of Test
Coding subset
Total Raw Score:
Standard Score:
WAIS Coding Completion Time (seconds):

Symbol Search Subset
Total Correct
Total Incorrect
Total Raw Score (#correct-#incorrect)
Standard Score
Symbol Search Completion Time (seconds):

WAIS Processing Speed Index (PSI) Summary
Sum of Scaled Scores:
PSI Composite Scores:
PSI Percentile Rank:
PSI Confidence Internal (90%)
　　　From　　　　　To
PSI Confidence Internal (95%)
　　　From　　　　　To

Parameter Name	Age
CRF Field	Age
CRF Description	Age
CRF Input Type	Number
NIND 2.0 CDE ID	C00008
NIND 2.0 CDE Name	Age value
IMPACT 1.5 CDE	Age = age
Variable Type	Numerical
Calculation Rule	Date of Injury – Date of Birth
Permissible Range	0-89
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	For patients who are older than 89 year old, age 90 is used due to HIPAA requirements

Age	Baseline
N	599
Mean	42.62
Median	42
Min	3
Max	90
SD	18.84
Missing/NA	0

Parameter Name	Sex
CRF Field	Sex
CRF Description	Gender
CRF Input Type	Radio button
NIND 2.0 CDE ID	C00035
NIND 2.0 CDE Name	Gender type
IMPACT 1.5 CDE	Sex
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Sex	Count at Baseline (N)
1 - Female	171
2 - Male	428
Missing/NA	0

Parameter Name	CountryOfBirth, *CountryOfBirthOther*
CRF Field	Country Of Birth
CRF Description	Country Of Birth (USA, Mexico, or Canada)
CRF Input Type	Radio button, *Text area*
NIND 2.0 CDE ID	C00005
NIND 2.0 CDE Name	Birth country name
IMPACT 1.5 CDE	Country Of Birth
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	Other (not in list), Unknown/Not reported
Comments	Issues may exist for free text entries

Country Of Birth	Count at Baseline (N)
US - USA	515
MX - Mexico	15
CA - Canada	1
USA, Mexico	*1*
Missing/NA	67
Country Of Birth (not in list) (text)	*60*

Parameter Name	CountryOfResidence, *CountryOfResidenceOther*
CRF Field	Country Of Residence
CRF Description	Country Of Residence (USA, Mexico, or Canada)
CRF Input Type	Radio button, *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	Other (not in list), Unknown/Not reported
Comments	Issues may exist for free text entries

Country Of Residence	Count at Baseline (N)
US - USA	580
MX - Mexico	2
CA - Canada	0
Missing/NA	17
Country Of Residence (not in list) (text)	4

Parameter Name	PrimaryLanguage, *PrimaryLanguageOther*
CRF Field	Primary Language
CRF Description	Primary language of patient
CRF Input Type	Dropdown, *Text area*
NIND 2.0 CDE ID	C00025
NIND 2.0 CDE Name	Language primary text
IMPACT 1.5 CDE	
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	Other (not in list), Unknown/Not reported
Comments	Issues may exist for free text entries

Primary Language	Count at Baseline (N)
ENG - English	540
ARA - Arabic	2
CAN - Cantonese	6
DUT - Dutch	1
FRE - French	2
GER - German	1
ITA - Italian	1
MAN – Mandarin	1
NAV - Navaho	1
POR – Portuguese	1
RUS - Russian	2
SAM – Samoan	1
SPA - Spanish	25
TAG – Tagalog	3
THA – Thai (Laotian)	1
Missing/NA	11
Primary Language (Not in list) (text)	*15*

Parameter Name	Ethnicity
CRF Field	Ethnicity
CRF Description	Ethnicity
CRF Input Type	Dropdown
NIND 2.0 CDE ID	C00020
NIND 2.0 CDE Name	Ethnicity USA category
IMPACT 1.5 CDE	Ethnicity
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Ethnicity	Count at Baseline (N)
HI - Hispanic or Latino	87
NH - Non Hispanic or Latino	428
UN - Unknown	1
Missing/NA	6

Parameter Name	Handedness
CRF Field	Handedness
CRF Description	Indicates whether the person is right or left handed
CRF Input Type	Dropdown
NIND 2.0 CDE ID	C00023
NIND 2.0 CDE Name	Hand preference type
IMPACT 1.5 CDE	Handed = handedness
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Handedness	Count at Baseline (N)
RH - Righthanded	498
LH - Lefthanded	39
BH - Both	11
Missing/NA	51

Subject ▸ Demographics ▸ Race

Parameter Name	Race
CRF Field	Race
CRF Description	Race
CRF Input Type	Checkbox
NIND 2.0 CDE ID	C00030; C00031
NIND 2.0 CDE Name	Race USA category; Race expanded category
IMPACT 1.5 CDE	Race
Variable Type	Categorical (multiple permitted)
Recommended Interpretation for missing/NA values	RaceNoInfo
Comments	No selection for multiple races/mixed races

Race	Count at Baseline (N)
American Indian	8
South/Central American Indian	0
North American Indian	7
Alaskan Native/Inuit	0
Alaskan Native	0
Inuit	0
Asian	29
South Asian (Indian subcontinent)	4
Far Eastern Asian	25
Black	55
African American	51
African	0
Afro Caribbean	0
Native Hawaiian/Pacific Islander	24
Hawaiian	2
Pacific Islander	24
White	501
North American	371
South American	36
European	84
Middle Eastern	8
White African	1
Oceanian (Australian or New Zealander)	1
Missing/NA	5

Subject	Demographics	Unable to obtain information (Race)

Parameter Name	RaceNoInfo, *RaceNoInfoOther*
CRF Field	Unable to obtain information (Reason)
CRF Description	Unable to obtain information about race (Reason)
CRF Input Type	Dropdown, *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Other CDEs have "Not reported", "Unknown", and "Other" in Race

Unable to obtain information (Race)	Count at Baseline (N)
RE - Refused	0
UN - Unknown by patient or family	0
DI - Discharged/expired before asked	5
OT - Other	1
Missing/NA	593
Other Reason (text)	*1*

Parameter Name	SesEduNoAdult
CRF Field	Number of years of school completed
CRF Description	Number of years of school completed by adult patient
CRF Input Type	Text area
NIND 2.0 CDE ID	C00015
NIND 2.0 CDE Name	Education years number
IMPACT 1.5 CDE	SES-EDUNo = Number of years of education completed
Variable Type	Numerical
Calculation Rule	
Permissible Range	0-30
Recommended Interpretation for missing/NA values	Not applicable (pediatric patient), Unknown/Not reported
Comments	Only applicable for adult patient age >16

Number of years of school completed	Baseline
N	508
Mean	13.78
Median	14
Min	2
Max	24
SD	2.96
Non-numerical/Out of range	3
Missing/NA	88

Parameter Name	SesEduTypeAdult, *SesEduTypeAdultNoInfo, SesEduTypeAdultNoInfoOther*
CRF Field	Highest diploma/degree
CRF Description	Highest education level of adult patient
CRF Input Type	Dropdown, *Dropdown, Text area*
NIND 2.0 CDE ID	C00012
NIND 2.0 CDE Name	Education level USA type
IMPACT 1.5 CDE	SES-EDUType = Highest level of education
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable (pediatric patient), Unable to obtain information , Unknown/Not reported
Comments	Only applicable for adult patient age >16 Should corroborate with Years of Education

Highest diploma/degree	Count at Baseline (N)
1 - None, not currently in school	45
2 - None, but currently in diploma or degree-oriented program	10
3 - Vocational training (no high school diploma or GED)	8
4 - GED	27
5 - High school diploma	226
6 - Vocational training (post high school)	32
7 - Associate's degree	32
8 - Bachelors degree	112
9 - Masters degree	38
10 - Doctoral degree	17
99 - Unable to obtain information	15
Missing/NA	37
Unable to obtain information (Reason)	*20*
RE - Refused	0
UN - Unknown by patient or family	2
DI - Discharged/expired before asked	18
OT - Other	0
Other Reason (text)	*1*

Parameter Name	SesEmpl, *SesEmplNoInfo, SesEmplNoInfoOther*
CRF Field	Employment
CRF Description	Employment status of adult patient
CRF Input Type	Dropdown, *Dropdown, Text area*
NIND 2.0 CDE ID	C00204
NIND 2.0 CDE Name	Employment status
IMPACT 1.5 CDE	SESEmpl = Employment
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable (pediatric patient), Unable to obtain information , Unknown/Not reported
Comments	Only applicable for adult patient age >16

Employment	Count at Baseline (N)
1 - Working full time (35 hrs or more/week, at least minimum wage)	221
2 - Working 20-34 hrs/week, at least minimum wage	51
3 - Working less than 20 hrs/week, at least minimum wage	23
4 - Temporary/odd jobs/less than minimum wage jobs	17
5 - Special employment (sheltered workshop, supportive employment, job coach)	1
6 - Unemployed	118
7 - Other	4
8 - Not in paid workforce (including child, retired, student, homemaker, disabled pre-injury)	122
99 - Unable to obtain information	12
Missing/NA	30
Unable to obtain information (Reason)	*16*
RE - Refused	0
UN - Unknown by patient or family	1
DI - Discharged/expired before asked	14
OT - Other	1
Other Reason (text)	*9*

Parameter Name	SesMar, *SesMarNoInfo, SesMarNoInfoOther*
CRF Field	Marital Status
CRF Description	Marital Status of adult patient
CRF Input Type	Dropdown, *Dropdown, Text area*
NIND 2.0 CDE ID	C00207
NIND 2.0 CDE Name	Marital or partner status
IMPACT 1.5 CDE	SESMAR = Marital status
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable (pediatric patient), Unable to obtain information , Unknown/Not reported
Comments	Only applicable for adult patient age >16

Marital Status	Count at Baseline (N)
1 - Single	292
2 - Married/living together/common law	188
3 - Separated	9
4 - Divorced	46
5 - Widowed	27
6 - Other	2
99 - Unable to obtain information	1
Missing/NA	34
Unable to obtain information (Reason)	*3*
RE - Refused	0
UN - Unknown by patient or family	0
DI - Discharged/expired before asked	2
OT - Other	1
Other Reason (text)	*3*

Parameter Name	SchoolStat, *SchoolStatOther, SchoolStatNoInfo, SchoolStatNoInfoOther*
CRF Field	School Status
CRF Description	School status of patient (both adult and child)
CRF Input Type	Dropdown, *Text area*, *Dropdown, Text area*
NIND 2.0 CDE ID	C00202
NIND 2.0 CDE Name	Education school participation status
IMPACT 1.5 CDE	SchoolStat = School status
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unable to obtain information , Unknown/Not reported
Comments	

School Status	Count at Baseline (N)
1 - Full time student (diploma/degree oriented/2 courses or more)	59
2 - Part time student (diploma/degree oriented)	14
3 - Elementary school student (0-8th grade)	6
4 - Secondary school student (9-12th grade)	10
5 - Special education	0
6 - Vocational program	2
7 - Other	5
8 - None	342
99 - Unable to obtain information	16
Missing/NA	145
School Status Other (text)	*4*
Unable to obtain information (Reason)	*16*
RE - Refused	0
UN - Unknown by patient or family	0
DI - Discharged/expired before asked	16
OT - Other	0
Other Reason (text)	*0*

Parameter Name	SesPrimAdult, *SesPrimAdultOther, SesPrimAdultNoInfo, SesPrimAdultNoInfoOther*
CRF Field	Primary person living with
CRF Description	Primary person living with adult patient
CRF Input Type	Dropdown, *Text area, Dropdown, Text area*
NIND 2.0 CDE ID	C00215
NIND 2.0 CDE Name	Living with person relationship type
IMPACT 1.5 CDE	SESPRIM = Persons living with
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable (pediatric patient), Unable to obtain information , Unknown/Not reported
Comments	Only applicable for adult patient age >16 May select multiple checkboxes

Primary person living with	Count at Baseline (N)
1 - Alone	132
2 - Spouse (including common law partner)	185
3 - Parents	80
4 - Siblings	11
5 - Child/children	19
6 - Significant other partner	29
7 - Roommates/friends	74
8 - Other patients (in hospital/nursing home)	0
9 - Other residents	10
10 - Group living situation, boarding house	4
11 - Personal care attendant	0
12 - Military barracks	0
13 - Homeless	16
14 - Other (incl. correctional facility inmates)	6
99 - Unable to obtain information	4
Missing/NA	29
Specify other resident	*79*
Unable to obtain information (Reason)	*6*
RE - Refused	0
UN - Unknown by patient or family	1
DI - Discharged/expired before asked	5
OT - Other	0
Other Reason (text)	*1*

Parameter Name	SesPrimChild, *SesPrimChildNoInfo,* *SesPrimChildNoInfoOther*
CRF Field	Living with
CRF Description	Living situation of juvenile patient
CRF Input Type	Dropdown, *Dropdown, Text area*
NIND 2.0 CDE ID	C00215
NIND 2.0 CDE Name	Living with person relationship type
IMPACT 1.5 CDE	SESPRIM = Persons living with
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable (adult patient), Unable to obtain information , Unknown/Not reported
Comments	Other CDEs use same CDE for adult and juvenile

Living situation of juvenile patient	Count at Baseline (N)
1 - Parents	26
2 - Other family members	1
3 - Adoptive parents	0
4 - Foster care	0
5 - Other	1
99 - Unable to obtain information	0
Missing/NA	571
Unable to obtain information (Reason)	*0*
RE - Refused	0
UN - Unknown by patient or family	0
DI - Discharged/expired before asked	0
OT - Other	0
Other Reason (text)	*0*

Parameter Name	SesEduNoFather
CRF Field	Number of years of school completed
CRF Description	Number of years of school completed by father of juvenile patient
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	0-30
Recommended Interpretation for missing/NA values	Not applicable (adult patient), Unknown/Not reported
Comments	Only applicable for juvenile patient age <16

Number of years of school completed	Baseline
N	12
Mean	13.42
Median	12.5
Min	8
Max	20
SD	3.32
Non-numerical/Out of range	0
Missing/NA	587

Parameter Name	SesEduTypeFather, *SesEduTypeFatherNoInfo, SesEduTypeFatherNoInfoOther*
CRF Field	Highest diploma/degree
CRF Description	Highest education level of father of juvenile patient
CRF Input Type	Dropdown, *Dropdown, Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable (adult patient), Unable to obtain information , Unknown/Not reported
Comments	Only applicable for juvenile patient age <16

Highest diploma/degree	Count at Baseline (N)
1 - None, not currently in school	2
2 - None, but currently in diploma or degree-oriented program	0
3 - Vocational training (no high school diploma or GED)	0
4 - GED	0
5 - High school diploma	6
6 - Vocational training (post high school)	0
7 - Associate's degree	1
8 - Bachelors degree	2
9 - Masters degree	0
10 - Doctoral degree	1
99 - Unable to obtain information	1
Missing/NA	586
Unable to obtain information (Reason)	*13*
RE - Refused	0
UN - Unknown by patient or family	0
DI - Discharged/expired before asked	12
OT - Other	1
Other Reason (text)	*2*

Parameter Name	SesEduNoMother
CRF Field	Number of years of school completed
CRF Description	Number of years of school completed by Mother of juvenile patient
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	0-30
Recommended Interpretation for missing/NA values	Not applicable (adult patient), Unknown/Not reported
Comments	Only applicable for juvenile patient age <16

Number of years of school completed	Baseline
N	13
Mean	12.69
Median	13
Min	6
Max	18
SD	3.59
Non-numerical/Out of range	0
Missing/NA	586

Parameter Name	SesEduTypeMother, *SesEduTypeMotherNoInfo, SesEduTypeMotherNoInfoOther*
CRF Field	Highest diploma/degree
CRF Description	Highest education level of mother of juvenile patient
CRF Input Type	Dropdown, *Dropdown, Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable (adult patient), Unable to obtain information , Unknown/Not reported
Comments	Only applicable for juvenile patient age <16

Highest diploma/degree	Count at Baseline (N)
1 - None, not currently in school	4
2 - None, but currently in diploma or degree-oriented program	0
3 - Vocational training (no high school diploma or GED)	0
4 - GED	0
5 - High school diploma	3
6 - Vocational training (post high school)	0
7 - Associate's degree	2
8 - Bachelors degree	3
9 - Masters degree	1
10 - Doctoral degree	0
99 - Unable to obtain information	0
Missing/NA	586
Unable to obtain information (Reason)	*12*
RE - Refused	0
UN - Unknown by patient or family	0
DI - Discharged/expired before asked	12
OT - Other	0
Other Reason (text)	*1*

Parameter Name	MilActiveYesNo
CRF Field	Subject on Active Duty?
CRF Description	
CRF Input Type	Radio button
NIND 2.0 CDE ID	C00221
NIND 2.0 CDE Name	Military service status
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not in military, Unknown/Not reported
Comments	More selections (reserve, retired) in NIND

Subject on Active Duty?	Count at Baseline (N)
1 - Yes	11
2 - No	445
Missing/NA	143

Parameter Name	MilServ
CRF Field	Branch of service
CRF Description	Branch of service of military patient
CRF Input Type	Dropdown
NIND 2.0 CDE ID	C00208
NIND 2.0 CDE Name	Military USA service branch type
IMPACT 1.5 CDE	MilServ = branch of military service
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not in military, Unknown/Not reported
Comments	No selection for Coast Guard/Other

Branch of service	Count at Baseline (N)
AF - Airforce	7
AR - Army	30
MA - Marine corps	10
NA - Navy	11
Missing/NA	541

Parameter Name	MilRank
CRF Field	Rank
CRF Description	Military rank of military patient
CRF Input Type	Dropdown
NIND 2.0 CDE ID	C00220
NIND 2.0 CDE Name	Military USA rank category
IMPACT 1.5 CDE	MilRank = Military rank
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not in military, Unknown/Not reported
Comments	

Rank	Count at Baseline (N)
JE - Junior enlisted (lower than NCO)	11
NC - NCO* (non-commissioned officers)	28
OF - Officer (and senior warrant officers)	11
Missing/NA	549

Parameter Name	MilMOS
CRF Field	Military occupation
CRF Description	Military occupational specialty of military patient
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	MilMOS = Military occupational service
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not in military, Unknown/Not reported
Comments	

Military occupation	Count at Baseline (N)
CO - Combat	13
NC - Non-combat	34
Missing/NA	552

Parameter Name	MilDeploy, *MilDeployOther*
CRF Field	Deployment
CRF Description	To where the military patient was deployed
CRF Input Type	Dropdown, *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not in military, Unknown/Not reported
Comments	Does not account for multiple deployments Does not account for past vs present deployments

Deployment	Count at Baseline (N)
NO - None	24
AG - Afghanistan	1
AF - Africa	0
GE - Germany	3
IQ - Iraq	3
OT - Other	13
Missing/NA	555
Other Deployment (text)	20

Parameter Name	SiteName
CRF Field	Site Name
CRF Description	
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	
Comments	This dataset contains only acute patients

Site Name	Count at Baseline (N)
SF - UCSF	338
PI - University of Pittsburgh	180
BR - UMC: Brackenridge	81
MS - Mount Sinai	0
Missing/NA	0

Parameter Name	PatientType
CRF Field	Patient Category: (Choose one)
CRF Description	Patient Category
CRF Input Type	Radio button
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	
Comments	This dataset contains only acute patients

Patient Category	Count at Baseline (N)
ED - ED Only	172
ICU - Hospital admit with ICU	206
WA - Hospital admit no ICU	221
RE - Rehab patient	0
Missing/NA	0

Parameter Name	InfConsTyp
CRF Field	Consent Source
CRF Description	Who signed the consent form
CRF Input Type	Dropdown
NIND 2.0 CDE ID	C02299
NIND 2.0 CDE Name	Informed consent type
IMPACT 1.5 CDE	InfCons-Typ = Type of informed consent
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Consent Source	Count at Baseline (N)
PT - Patient	451
LS - Legal surrogate	72
PA - Parent	52
GU - Guardian	0
FM - Other family member	21
AW - Enrolled under approved waiver	2
Missing/NA	1

Parameter Name	InfConsWhen
CRF Field	Timing of consent
CRF Description	Whether consent was before of after enrollment in study
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	InfCons-Conf = Confirmation of consent
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable (pediatric patient), Unknown/Not reported
Comments	

Timing of consent	Count at Baseline (N)
WB - Written Informed Consent BEFORE Enrollment	584
WA - Written Informed Consent AFTER Enrollment	6
Missing/NA	9

Parameter Name	InfConsWhenPediatric
CRF Field	Timing of consent for pediatric patient
CRF Description	Whether assent was before or after enrollment in study (pediatric patient)
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	InfCons-Conf = Confirmation of consent
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable (adult patient), Unknown/Not reported
Comments	

Timing of consent for pediatric patient	Count at Baseline (N)
WB - Written Informed Consent BEFORE Enrollment	52
WA - Written Informed Consent AFTER Enrollment	0
Missing/NA	547

Parameter Name	InfConsBy, *InfConsByOther*
CRF Field	Consented by:
CRF Description	Which staff person obtained the consent
CRF Input Type	Dropdown, *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Consented by	Count at Baseline (N)
MD - MD	14
RN – RN	174
RA - Research Assistant	400
OT - Other	8
Missing/NA	3
Specify other consent if not in list (text)	9

Parameter Name	InfConsTimeSinceInj
CRF Field	Time Since Injury (Informed Consent)
CRF Description	Time Since Injury
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Date & Time of Informed Consent– Date & Time of Injury
Permissible Range	> 0
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Related CDE is Date and time written consent signed

Time Since Injury (Informed Consent)	Time (hours)
N	585
Mean	348.17
Median	16.92
Min	0
Max	87674.25
SD	5124.34
Out of range	4
Missing/NA	10

Parameter Name	ConsentWithdrawn
CRF Field	Consent Withdrawn
CRF Description	
CRF Input Type	Checkbox
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

Consent Withdrawn	Count at Baseline (N)
N	4
Missing/NA	595

Parameter Name	InfConsTimeSinceInj
CRF Field	Time Since Injury (Consent withdrawn)
CRF Description	
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Date & Time of Consent Withdrawn– Date & Time of Injury
Permissible Range	> 0
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	Related CDE is Date and time withdrawn consent

Time Since Injury (Consent withdrawn)	Time (hours)
N	2
Mean	
Median	
Min	
Max	
SD	
Out of range	1
Missing/NA	596

Parameter Name	ConsentData, ConsentPlasma, ConsentDNA, ConsentMRI, ConsentOutcomeMeasures
CRF Field	Consented for:
CRF Description	Consent obtained for
CRF Input Type	Checkbox
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Consented for	Count at Baseline (N)
Data	597
Plasma	502
DNA	512
MRI	480
Outcome Measures	588

Parameter Name	MedHistCardio, *MedHistCardioOther*
CRF Field	010. Cardiovascular:
CRF Description	Medical Hx: Type of cardiovascular disease
CRF Input Type	Checklist, *Text area*
NIND 2.0 CDE ID	C00312
NIND 2.0 CDE Name	Body system category (Cardiovascular)
IMPACT 1.5 CDE	MEDHIST = Medical History (Cardiovascular (010))
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	No medical history in Cardiovascular, Unknown/Not reported
Comments	

010. Cardiovascular:	Count at Baseline (N)
011. Congenital heart disease	5
012. Arrhythmia	26
013. Ischemic heart disease	11
014. Valvular heart disease	3
015. Hypertension	148
016. Thromboembolic	4
017. Peripheral vascular disease	10
019. Other	91
Missing/NA	402
Other (text)	*118*

Parameter Name	MedHistEndocrine, *MedHistEndocrineOther*
CRF Field	020. Endocrine:
CRF Description	Med Hx: Types of endocrine diseases
CRF Input Type	Checklist, *Text area*
NIND 2.0 CDE ID	C00312
NIND 2.0 CDE Name	Body system category (Endocrine)
IMPACT 1.5 CDE	MEDHIST = Medical History (Endocrine (020))
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	No medical history in Endocrine, Unknown/Not reported
Comments	

020. Endocrine:	Count at Baseline (N)
021. Thyroid disorder	30
022. IDDM (Type I)	14
023. NIDDM (Type II)	38
029. Other	14
Missing/NA	514
Other (text)	*24*

Parameter Name	MedHistEyeEarNoseThroat, *MedHistEyeEarNoseThroatOther*
CRF Field	030. Eye, Ear, Nose & Throat:
CRF Description	Med Hx: Types of Eye, ear, nose, throat diseases
CRF Input Type	Checklist, *Text area*
NIND 2.0 CDE ID	C00312
NIND 2.0 CDE Name	Body system category (Ears, Nose, Mouth, Throat)
IMPACT 1.5 CDE	MEDHIST = Medical History (Eye, Ear, Nose, Throat (030))
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	No medical history in Ears, Nose, Mouth, Throat, Unknown/Not reported
Comments	

030. Eye, Ear, Nose & Throat:	Count at Baseline (N)
031. Sinusitis	18
032. Vision abnormality	44
033. Hearing deficit	19
039. Other	38
Missing/NA	498
Other (text)	*71*

Parameter Name	MedHistGastrointestinal, *MedHistGastrointestinalOther, MedHistGastrointestinalDiarrhea*
CRF Field	040. Gastrointestinal:
CRF Description	Med Hx: Types of Gastrointestinal diseases
CRF Input Type	Checklist, *Text area, Text area*
NIND 2.0 CDE ID	C00312
NIND 2.0 CDE Name	Body system category (Gastrointestinal)
IMPACT 1.5 CDE	MEDHIST = Medical History (Gastrointestinal (040))
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	No medical history in Gastrointestinal, Unknown/Not reported
Comments	

040. Gastrointestinal:	Count at Baseline (N)
041. GERD	49
042. GI bleed	6
043. Inflammatory bowel disease	5
044. Diarrhea secondary to	2
049. Other	53
Missing/NA	501
Other (text)	*56*
Diarrhea secondary to: (text)	*6*

Parameter Name	MedHistHematologic, *MedHistHematologicOther*
CRF Field	050. Hematologic:
CRF Description	Med Hx: Types of Hematologic diseases
CRF Input Type	Checklist, *Text area*
NIND 2.0 CDE ID	C00312
NIND 2.0 CDE Name	Body system category (Hematologic/Lymphatic)
IMPACT 1.5 CDE	MEDHIST = Medical History (Hematologic (050))
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	No medical history in Hematologic, Unknown/Not reported
Comments	

050. Hematologic:	Count at Baseline (N)
051. Anemia	32
052. HIV positive	14
053. AIDS	1
054. Sickle cell disease	0
055. Coagulopathy	2
059. Other	19
Missing/NA	537
Other (text)	*24*

Parameter Name	MedHistHepatic, *MedHistHepaticOther*
CRF Field	060. Hepatic:
CRF Description	Med Hx: Types of hepatic diseases
CRF Input Type	Checklist, *Text area*
NIND 2.0 CDE ID	C00312
NIND 2.0 CDE Name	Body system category (no match)
IMPACT 1.5 CDE	MEDHIST = Medical History (Hepatic (060))
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	No medical history in Hepatic, Unknown/Not reported
Comments	

060. Hepatic:	Count at Baseline (N)
061. Insufficiency	1
062. Failure	1
063. Hepatitis	29
064. Cirrhosis	12
069. Other	13
Missing/NA	552
Other (text)	*37*

Parameter Name	MedHistMusculoskeletal, *MedHistMusculoskeletalOther*
CRF Field	070. Musculoskeletal:
CRF Description	Med Hx: Types of Musculoskeletal diseases
CRF Input Type	Checklist, *Text area*
NIND 2.0 CDE ID	C00312
NIND 2.0 CDE Name	Body system category (Musculoskeletal)
IMPACT 1.5 CDE	MEDHIST = Medical History (Musculoskeletal (070))
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	No medical history in Musculoskeletal, Unknown/Not reported
Comments	

070. Musculoskeletal:	Count at Baseline (N)
071. Arthritis	56
072. Spasticity	0
073. Pressure ulcers	1
079. Other	92
Missing/NA	469
Other (text)	*99*

Parameter Name	MedHistNeurologic, *MedHistNeurologicOther*
CRF Field	080. Neurologic:
CRF Description	Med Hx: Types of neurologic diseases
CRF Input Type	Checklist, *Text area*
NIND 2.0 CDE ID	C00312
NIND 2.0 CDE Name	Body system category (Neurological)
IMPACT 1.5 CDE	MEDHIST = Medical History (Neurologic (080))
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	No medical history in Neurological, Unknown/Not reported
Comments	

080. Neurologic:	Count at Baseline (N)
Spinal cord injury	24
Vertebral injury	12
Cerebral vascular anomaly	1
Tumor	4
081. Cerebrovascular Accident	9
082. Transient Ischemic Attacks	6
083. Seizures	57
083. Seizures-Febrile	2
083. Seizures-Posttraumatic	7
083. Seizures-Idiopathic	2
083. Seizures-Alcohol	19
084. Epilepsy: partial	1
085: Epilepsy: focal	0
086. Epilepsy: other	4
087. Headache (non migraine)	21
088. Migraine headaches	44
089. Previous TBI	117
899. Other	38
Missing/NA	388
Other (text)	*111*

Parameter Name	MedHistOncologic, *MedHistOncologicOther*
CRF Field	090. Oncologic:
CRF Description	Med Hx: Types of oncologic diseases
CRF Input Type	Checklist, *Text area*
NIND 2.0 CDE ID	C00312
NIND 2.0 CDE Name	Body system category (no match)
IMPACT 1.5 CDE	MEDHIST = Medical History (Oncologic (090))
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	No medical history in Oncologic, Unknown/Not reported
Comments	No data on whether past or present

090. Oncologic:	Count at Baseline (N)
091. Leukemia	1
092. Lymphoma	3
093. Breast Cancer	5
094. Prostate Cancer	2
095. Lung Cancer	1
096. GI Cancer	0
097. Kidney Cancer	1
098. Cancer (other)	18
099. Other	23
Missing/NA	549
Other (text)	*47*

Parameter Name	MedHistPulmonary, *MedHistPulmonaryOther*
CRF Field	100. Pulmonary:
CRF Description	Med Hx: Types of pulmonary diseases
CRF Input Type	Checklist, *Text area*
NIND 2.0 CDE ID	C00312
NIND 2.0 CDE Name	Body system category (Respiratory)
IMPACT 1.5 CDE	MEDHIST = Medical History (Pulmonary (100))
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	No medical history in Pulmonary, Unknown/Not reported
Comments	

100. Pulmonary:	Count at Baseline (N)
101. COPD	14
102. Asthma	70
103. Pneumonia	24
104. Tuberculosis	9
109.Other	22
Missing/NA	480
Other (text)	*41*

Parameter Name	MedHistPsychiatric, *MedHistPsychiatricOther*
CRF Field	110. Psychiatric:
CRF Description	Med Hx: Types of psychiatric diseases
CRF Input Type	Checklist, *Text area*
NIND 2.0 CDE ID	C00312
NIND 2.0 CDE Name	Body system category (Psychiatric)
IMPACT 1.5 CDE	MEDHIST = Medical History (Psychiatric (110))
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	No medical history in Psychiatric, Unknown/Not reported
Comments	Self-report only, not clinical diagnosis

110. Psychiatric:	Count at Baseline (N)
111. Anxiety	77
112. Depression	129
113. Sleep disorder	44
114. Schizophrenia	5
115. Other psychiatric disorder	22
119. Other	17
Missing/NA	429
Other (text)	*52*

Parameter Name	MedHistRenal, *MedHistRenalOther*
CRF Field	120. Renal:
CRF Description	Med Hx: Types of renal diseases
CRF Input Type	Checklist, *Text area*
NIND 2.0 CDE ID	C00312
NIND 2.0 CDE Name	Body system category (no match)
IMPACT 1.5 CDE	MEDHIST = Medical History (Renal (120))
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	No medical history in Renal, Unknown/Not reported
Comments	

120. Renal:	Count at Baseline (N)
121. Insufficiency	5
122. Failure	10
123. Chronic UTI's	2
129. Other	28
Missing/NA	558
Other (text)	*39*

Parameter Name	MedHistSocialHistory, *MedHistSocialHistoryOther*
CRF Field	130. Social history:
CRF Description	Med Hx: Social Hx: Use of tobacco, alcohol or drugs
CRF Input Type	Checklist, *Text area*
NIND 2.0 CDE ID	C00711, C00706, C00717
NIND 2.0 CDE Name	Tobacco prior use indicator, Alcohol prior use indicator, Drug or substance prior illicit use indicator
IMPACT 1.5 CDE	MEDHIST = Medical History (Social History (130))
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	No medical history in Social History, Unknown/Not reported
Comments	Substance use frequency not recorded Alcohol use vs abuse not specified

130. Social history:	Count at Baseline (N)
131. Tobacco use	191
132. Alcohol use	308
133. Drug use	131
139. Other	8
Missing/NA	241
Other (text)	*217*

Parameter Name	MedHistDevelopmentalHistory, *MedHistDevelopmentalHistoryOther*
CRF Field	140. Developmental history:
CRF Description	Med Hx: Types of developmental disorders
CRF Input Type	Checklist, *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	MEDHIST = Medical History (Developmental History (140))
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	No medical history in Developmental History, Unknown/Not reported
Comments	

140. Developmental history:	Count at Baseline (N)
141. Learning disabilities	16
142. Attention deficit/hyperactivity disorder	36
143. Developmentally Delayed	6
144. Other developmental disorder	6
149. Other	2
Missing/NA	542
Other (text)	*23*

Parameter Name	PresArrivalMethod, *PresArrivalMethodOther*
CRF Field	Method of Arrival
CRF Description	Presentation: Method of arrival
CRF Input Type	Radio button, *Text area*
NIND 2.0 CDE ID	C05418
NIND 2.0 CDE Name	Transport to hospital type
IMPACT 1.5 CDE	TRANSMOD = Mode of Transport
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Method of Arrival	Count at Baseline (N)
1 - Ambulance	478
2 - Helicopter	93
3 - Medical mobile team	0
4 - Walk in or drop off	25
5 - Other	0
Missing/NA	3
Specify other method of arrival: (text)	*0*

Parameter Name	PresHypotension
CRF Field	Hypotension in field?
CRF Description	Presentation: Hypotension in field
CRF Input Type	Radio button
NIND 2.0 CDE ID	C05453
NIND 2.0 CDE Name	Hypotensive episode indicator
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not reported
Comments	

Hypotension in field?	Count at Baseline (N)
1 - Yes	18
0 - No	493
2 - Unknown	82
Missing/NA	6

Parameter Name	PresHypoxia
CRF Field	Hypoxia in field?
CRF Description	Hypoxia in field?
CRF Input Type	Radio button
NIND 2.0 CDE ID	C05457
NIND 2.0 CDE Name	Hypoxic episode indicator
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not reported
Comments	

Hypoxia in field?	**Count at Baseline (N)**
1 - Yes	15
0 - No	484
2 - Unknown	95
Missing/NA	5

Parameter Name	PresIntubation
CRF Field	Intubated in field?
CRF Description	Intubated in field?
CRF Input Type	Radio button
NIND 2.0 CDE ID	C05457
NIND 2.0 CDE Name	Hypoxic episode indicator
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not reported
Comments	

Intubated in field?	Count at Baseline (N)
1 - Yes	37
0 - No	512
2 - Unknown	45
Missing/NA	5

Parameter Name	GcsPreHospScore, *GCSPrehospScoreUnknown*
CRF Field	Prehospital GCS
CRF Description	Prehospital GCS
CRF Input Type	Text area, *Checkbox*
NIND 2.0 CDE ID	C01016
NIND 2.0 CDE Name	GCS Total score (not time specific)
IMPACT 1.5 CDE	GCS_PreHosp = GCS prehospital
Variable Type	Numerical
Calculation Rule	
Permissible Range	3-15 (integer)
Recommended Interpretation for missing/NA values	Not reported
Comments	In 4 records with 3T-10T, only numerical values were kept.

GCS Score	Prehospital	ED Arrival	ED Discharge
N	491	561	504
Mean	13.21	13.76	14.03
Median	15	15	15
Min	3	3	3
Max	15	15	15
SD	3.19	2.85	2.92
Out of range (999 – Not found)	4	0	0
Out of range (non-numerical)	1	0	0
Out of range (0)	0	38	95
Missing/NA	103	0	0
GCS Unknown/untestable	89	38	95

Parameter Name	GcsPreHospScoreTimeSinceInj
CRF Field	Time Since Injury (Prehospital GCS)
CRF Description	Time Since Injury (Prehospital GCS)
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Date & Time of Prehospital GCS – Date & Time of Injury
Permissible Range	> 0
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

Time Since Injury (Prehospital GCS)	Time (hours)
N	459
Mean	1.54
Median	0.32
Min	0
Max	64.75
SD	4.85
Out of range	7
Missing/NA	133

Parameter Name	PresTBIRef
CRF Field	Presentation
CRF Description	Presentation: To which type of hospital
CRF Input Type	Radio button
NIND 2.0 CDE ID	C05405
NIND 2.0 CDE Name	Hospital presentation type
IMPACT 1.5 CDE	TBIRef = Referral
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Presentation	Count (N)
1 - Primary-Directly to Study Hospital	483
2 - Secondary-To First Hospital, then to Study Hospital	110
Missing/NA	6

Parameter Name	PresFHospTimeSinceInj, PresSTHospTimeSinceInj
CRF Field	Time Since Injury (Arrival First Hospital), Time Since Injury (Arrival Study Hospital)
CRF Description	Time Since Injury (Arrival First Hospital), Time Since Injury (Arrival Study Hospital)
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Date & Time of Arrival at Hospital – Date & Time of Injury
Permissible Range	> 0
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

Time Since Injury (Arrival at Hospital)	First Hospital (hours)	Study Hospital (hours)
N	100	591
Mean	3.26	2.47
Median	1	0.75
Min	0	0
Max	59.05	65.75
SD	7.78	5.35
Out of range	5	1
Missing/NA	494	7

Parameter Name	PresLateTimeSinceInj
CRF Field	Time Since Injury (Late Presentation)
CRF Description	Time Since Injury (Late Presentation)
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Date & Time of Late Presentation – Date & Time of Injury
Permissible Range	> 0
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

Time Since Injury (Late Presentation)	Time (hours)
N	1
Mean	35.03
Median	
Min	
Max	
SD	
Out of range	0
Missing/NA	598

Parameter Name	PresLateReason
CRF Field	Reason for Presentation
CRF Description	Reason for Presentation
CRF Input Type	Radio button
NIND 2.0 CDE ID	C05409
NIND 2.0 CDE Name	Injury presentation reason
IMPACT 1.5 CDE	PresReason = Reason for presentation
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

Reason for Presentation	Count (N)
1 - Professional referral	1
2 - Self referral with complaints	1
3 - Routine screening	0
4 - Self referral on advice significant other	0
5 - Repatriation	0
Missing/NA	597

Parameter Name	PresLateReasonProfRef
CRF Field	If Professional referral, which
CRF Description	Late Presentation: Which professional referral
CRF Input Type	Radio button
NIND 2.0 CDE ID	C05410
NIND 2.0 CDE Name	Injury presentation professional referral category
IMPACT 1.5 CDE	Professional referral
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

Late Presentation: Which professional referral	Count (N)
1 - Hospital	1
2 - GP	0
3 - Other caretaker	0
Missing/NA	598

Parameter Name	PresLateInitMedCar
CRF Field	Hospitalization:
CRF Description	Late Presentation: Hospitalization directly after injury?
CRF Input Type	Radio button
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

Hospitalization	Count (N)
1 - Yes	64
0 - No	3
Missing/NA	532

Parameter Name	PresLateInitMedType
CRF Field	If no: Outpatient treatment:
CRF Description	Late Presentation: Outpatient treatment if no initial hospitalization:
CRF Input Type	Radio button
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

Outpatient treatment	Count (N)
1 - None	0
2 - Emergency Room	3
3 - Doctor's Office	0
4 - Sick Bay (military)	0
5 - Other health care provider	0
6 - Infirmary (if incarcerated)	0
Missing/NA	596

Parameter Name	InjType
CRF Field	Injury Type
CRF Description	Injury: Type of Injury
CRF Input Type	Radio button
NIND 2.0 CDE ID	C05420
NIND 2.0 CDE Name	Traumatic brain injury type
IMPACT 1.5 CDE	InjType = Type of injury
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Injury Type	Count (N)
1 - Closed	590
2 - Penetrating	5
3 - Blast	1
Missing/NA	3

Parameter Name	InjIntention
CRF Field	Intention
CRF Description	Injury: Intention
CRF Input Type	Radio button
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	InjIntent = Intent of injury
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Intention	Count (N)
1 - Unintentional	597
2 - Intentional	72
3 - Undetermined	15
Missing/NA	15

Parameter Name	InjMotorVehicle, *InjMotorVehiclePerson*
CRF Field	Motor vehicle traffic accidents
CRF Description	Type of Motor Vehicle accident causing injury
CRF Input Type	Checklist, *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	Must recode for individual analysis

Motor vehicle traffic accidents	Count (N)
810 Motor vehicle vs. train	0
811 Motor vehicle vs. motor vehicle re-entering road	4
812 Motor vehicle vs. motor vehicle on the road	41
813 Motor vehicle vs. non-motor vehicle	22
814 Motor vehicle vs. pedestrian	42
815 Motor vehicle vs. object on the road	15
816 Motor vehicle loss of control on the road	36
819 Motor vehicle traffic accident, general	38
.0 Driver of motor vehicle	40
.1 Passenger in motor vehicle	22
.2 Driver of motorcycle	29
.3 Passenger on motorcycle	3
.4 Occupant of streetcar	0
.5 Rider of animal or cart	3
.6 Pedal cyclist	78
.7 Pedestrian	31
.8 Other specified person	2
.9 Unspecified person	0
Missing/NA	338
Other Person (text)	*20*

Parameter Name	InjFalls
CRF Field	Falls (Accidental)
CRF Description	Type of fall causing injury
CRF Input Type	Checklist
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	Must recode for individual analysis

Falls (Accidental)	Count (N)
884 Fall from one level to another	84
885 Fall on same level from slip, trip, or stumble	76
886 Fall on same level from contact with person	2
888 Fall, general	56
Missing/NA	382

Parameter Name	InjStriking
CRF Field	Striking against or struck by person or object (Accidental)
CRF Description	Type of striking incident causing injury
CRF Input Type	Checklist
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	Must recode for individual analysis

Striking against or struck by person or object (Accidental)	Count (N)
917.0 In sports (tackles)	6
917.1 Caused by crowd, collective fear or panic	0
917.9 Other	11
Missing/NA	582

Parameter Name	InjCutting
CRF Field	Cutting and piercing instruments (Accidental)
CRF Description	Type of cutting or piercing object causing injury
CRF Input Type	Checklist
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	Must recode for individual analysis

Cutting and piercing instruments (Accidental)	Count (N)
920.0 Powered lawn mower	0
920.1 Other powered hand tools	0
920.2 Powered household appliances	0
920.3 Knives, swords, and daggers	0
920 Cutting and piercing, general	1
986 Undetermined if accidental or intentional	0
Missing/NA	598

Parameter Name	InjOtherPersons
CRF Field	Injury Purposely Inflicted by Other Persons
CRF Description	Type of injury inflicted by other person
CRF Input Type	Checklist
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	Must recode for individual analysis

Injury Purposely Inflicted by Other Persons	Count (N)
960.0 Unarmed fight or brawl	41
960.1 Rape	0
961 Assault by corrosive or caustic substance	0
965 Assault by firearms and explosives	0
966 Assault by cutting and piercing instruments	1
967 Child and adult battering/other maltreatment	2
968 Assault by other or unspecified means	30
968.0 Assault by fire	1
968.1 Assault by pushing from a high place	1
968.2 Assault by striking by blunt or thrown object	9
968.3 Assault by hot liquid	0
968.4 Assault by criminal neglect	0
968.5 Assault by transport vehicle	0
968.6 Assault by air gun	0
968.7 Assault by human bite	0
968.8 Assault by OTHER SPECIFIED means	0
968.9 Assault by UNSPECIFIED means	1
Missing/NA	504

Parameter Name	InjOtherAccidental
CRF Field	Other accidental causes of injury
CRF Description	Other accidental causes of injury
CRF Input Type	Checklist
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

Other accidental causes of injury	Count (N)
807 Railway accident	0
821 Motor vehicle off-road non-traffic accident	6
825 Motor vehicle accident – not traffic related	5
829 Other vehicle accident	35
876 Misadventure during medical care	0
899 Accident caused by fire	0
900 Environmental – excessive heat	0
906 Injury caused by animal	2
910 Accidental drowning and submersion	1
913 Accidental mechanical suffocation	0
916 Struck accidentally by falling object	3
918 Accidentally caught in or between objects	0
919 Accident caused by machinery	1
924 Accident caused by hot or caustic liquids or gases	0
925 Accident caused by electrical current	0
928 Other environmental or accidental causes	3
929 Late effects of accidental injury	0
Missing/NA	544

Parameter Name	InjFirearms
CRF Field	Firearms, air guns, and explosives
CRF Description	Type of Firearm accident causing injury
CRF Input Type	Checklist
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

Firearms, air guns, and explosives	Count (N)
922 Accident caused by firearm and air gun missile	1
923 Accident caused by explosive material	1
985 Unknown if accidental or intentional	1
Missing/NA	597

Parameter Name	InjSelfInflicted
CRF Field	Suicide and Self-Inflicted Injury
CRF Description	Type of self-inflicted accident causing injury
CRF Input Type	Checklist
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

Suicide and Self-Inflicted Injury	Count (N)
950 Poisoning by solid and liquid substances	0
953 Hanging, strangulation, suffocation	0
956 Cutting and piercing instrument	0
958 Other and unspecified means	0
959 Late effects of self-inflicted injury	0
Missing/NA	599

Parameter Name	InjPlace
CRF Field	Place of Injury
CRF Description	Place injury occurred
CRF Input Type	Radio button
NIND 2.0 CDE ID	C05426
NIND 2.0 CDE Name	Injury place of occurrence type
IMPACT 1.5 CDE	InjPlace = Place of injury
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not reported
Comments	

Place of injury	Count (N)
1 - Home	119
2 - Street/highway	378
3 - Work/school	30
4 - Recreational	49
5 - Military deployment	0
6 - Other	15
7 - Unknown	2
Missing/NA	6

Parameter Name	InjSafetyHelmet
CRF Field	Helmet Used
CRF Description	Was safety helmet on at time of accident. (Y/N/NA)
CRF Input Type	Radio button
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	SafProt = Safety and protection (not specific)
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not reported
Comments	Applicable only for certain injuries

Helmet Used	Count (N)
1 - Yes	66
0 - No	90
3 – Not Applicable	434
2 - Unknown	6
Missing/NA	3

Parameter Name	InjSafetyAirbag
CRF Field	Airbag Deployed
CRF Description	Did injury involve airbag. (Y/N/NA/UNK)
CRF Input Type	Radio button
NIND 2.0 CDE ID	C05435
NIND 2.0 CDE Name	Airbag deployed indicator
IMPACT 1.5 CDE	SafProt = Safety and protection (not specific)
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not reported
Comments	Applicable only for certain injuries

Airbag Deployed	Count (N)
1 - Yes	24
0 - No	29
3 – Not Applicable	504
2 - Unknown	37
Missing/NA	5

Parameter Name	InjSafetySeatbelt
CRF Field	Seatbelt Used
CRF Description	Was seatbelt on at time of injury (Y/N/NA/UNK)
CRF Input Type	Radio button
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	SafProt = Safety and protection (not specific)
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not reported
Comments	Applicable only for certain injuries

Seatbelt Used	Count (N)
1 - Yes	50
0 - No	35
3 – Not Applicable	494
2 - Unknown	14
Missing/NA	6

Parameter Name	InjIssScore
CRF Field	ISS Score
CRF Description	ISS Score. Calculated as the sum of squares of the AIS scores.
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Sum of squares of the AIS scores
Permissible Range	0-75 (integer)
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Not available for ED discharge patients

ISS Score	Original entry	Recalculate
N	599	550
Mean	12.11	12.79
Median	10	11
Min	0	0
Max	177	59
SD	13.30	11.31
Missing/NA	0	49

Parameter Name	InjDiagnosis
CRF Field	Injury/Diagnosis
CRF Description	Injury/Diagnosis
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Text
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Only UCSF site

Parameter Name	InjBodyRegion
CRF Field	Body Region
CRF Description	Body Region injured
CRF Input Type	Dropdown
NIND 2.0 CDE ID	C05449
NIND 2.0 CDE Name	Abbreviated Injury Scale body region category
IMPACT 1.5 CDE	ExtraCranInj = Extracranial Injuries
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Not available for ED discharge patients

Body Region	Count (N)
1 - Head or neck	1135
2 - Face	483
3 - Chest	220
4 - Abdominal or pelvic contents	111
5 - Extremities or pelvic girdle	419
6 - External	409
Missing/NA	45

Parameter Name	InjAIS
CRF Field	AIS
CRF Description	AIS score
CRF Input Type	Dropdown
NIND 2.0 CDE ID	C05450
NIND 2.0 CDE Name	Abbreviated Injury Scale body region score
IMPACT 1.5 CDE	InjSev = Injury Severity
Variable Type	Numerical
Calculation Rule	
Permissible Range	1-6 (integer)
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Not available for ED discharge patients AIS Head score does not differentiate between concussion and lesion

AIS	Count (N)
1	835
2	665
3	583
4	253
5	66
6	0
Missing/NA	420

Parameter Name	InjICD9
CRF Field	ICD9
CRF Description	ICD9 code for injury
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Text
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Not available for ED discharge patients

Parameter Name	LOCAssmtTimeSinceInj
CRF Field	Time Since Injury (LOC Assessment)
CRF Description	Time Since Injury (LOC Assessment)
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Date & Time of LOC Assessment – Date & Time of Injury
Permissible Range	> 0
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

Time Since Injury (LOC Assessment)	Time (hours)
N	184
Mean	26.48
Median	9.07
Min	0
Max	297.48
SD	45.96
Out of range	3
Missing/NA	412

Parameter Name	LOCTimeAssmt
CRF Field	Time of assessment
CRF Description	LOC: Time of assessment
CRF Input Type	Radio button
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Time of assessment	Count (N)
1 - ED Discharge	325
2 - ICU Discharge	33
3 - Hospital Discharge	142
Missing/NA	99

Parameter Name	LOCReportedBy
CRF Field	LOC Reported By
CRF Description	
CRF Input Type	Radio button
NIND 2.0 CDE ID	C01032
NIND 2.0 CDE Name	Loss of consciousness reporter type
IMPACT 1.5 CDE	TBILOC = Occurrence of loss of consciousness
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Caretaker could be witness or paramedic

LOC Reported By	Count (N)
1 - Patient	453
2 - Relative/friend/caretaker	122
Missing/NA	24

Parameter Name	LOCLossOfConsciousness
CRF Field	Loss Of Consciousness
CRF Description	LOC: Did the patient loose Consciousness?
CRF Input Type	Radio button
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	TBILOC = Occurrence of loss of consciousness
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not reported
Comments	

Loss Of Consciousness	Count (N)
1 - Yes	412
0 - No	133
2 - Unknown	46
Missing/NA	8

Parameter Name	LOCDuration
CRF Field	LOC Duration
CRF Description	LOC: Duration
CRF Input Type	Radio button
NIND 2.0 CDE ID	C01053
NIND 2.0 CDE Name	Loss of consciousness duration range
IMPACT 1.5 CDE	LOCDur = Duration of Loss of Consciousness
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not reported
Comments	

LOC Duration	Count (N)
1 - None	133
2 - <1 minute	59
3 - 1-29 minutes	174
4 - 30-59 minutes	22
5 - 1-24 hours	23
6 - >24 hours	21
7 - >7 days	7
8 - Unknown	151
Missing/NA	9

| Injury History | LOC PTA | LOC Lucid Interval |

Parameter Name	LOCLucidInterval
CRF Field	LOC Lucid Interval
CRF Description	LOC: Did the patient have a Lucid Interval
CRF Input Type	Radio button
NIND 2.0 CDE ID	C01054
NIND 2.0 CDE Name	Lucid interval indicator
IMPACT 1.5 CDE	LucInt = Lucid Interval
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not reported
Comments	

LOC Lucid Interval	Count (N)
1 - Yes	90
2 - No	465
Missing/NA	44

Parameter Name	LOCPTA
CRF Field	PTA (Post Traumatic Amnesia)
CRF Description	LOC: Did the patient experience Post Traumatic Amnesia
CRF Input Type	Radio button
NIND 2.0 CDE ID	C01037
NIND 2.0 CDE Name	Post traumatic amnesia indicator
IMPACT 1.5 CDE	TBIPTA = Occurrence of Post Traumatic Amnesia
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

PTA (Post Traumatic Amnesia)	Count (N)
1 - Yes	90
0 - No	465
Missing/NA	44

Parameter Name	LOCPTADuration
CRF Field	PTA Duration
CRF Description	LOC: Duration of PTA
CRF Input Type	Radio button
NIND 2.0 CDE ID	C01055
NIND 2.0 CDE Name	Post traumatic amnesia duration range
IMPACT 1.5 CDE	PTADur = Duration of PTA
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not reported
Comments	

LOC Duration	Count (N)
1 - None	176
2 - <1 minute	25
3 - 1-29 minutes	112
4 - 30-59 minutes	42
5 - 1-24 hours	55
6 - >24 hours	23
7 - >7 days	4
8 - Unknown	152
Missing/NA	10

Parameter Name	TBIHospitalized, TBICarAccident, TBIFall, TBISport, TBIFight, TBIExplosion, TBILoc, TBILocMemoryGap
CRF Field	
CRF Description	TBI Screen Q1: Hospitalized for head/neck injury, TBI Screen Q2: Injured head/neck in moving vehicle, TBI Screen Q3: Injured head/neck from fall or being hit, TBI Screen Q4:Injured head/neck doing sports, TBI Screen Q5: Injured head/neck in fight or being shaken, TBI Screen Q6: Been near explosion, TBI Screen Q7: Knocked unconscious (not drug OD or chocked), TBI Screen Q8: Dazed or gap in memory from injuries
CRF Input Type	Radio button
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	HistTBI = History of previous TBI exposure
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

TBI Screen	Q1 (N)	Q2 (N)	Q3 (N)	Q4 (N)	Q5 (N)	Q6 (N)	Q7 (N)	Q8 (N)
1 - Yes	161	102	116	87	80	36	135	92
0 - No	413	470	455	482	493	535	192	203
Missing/NA	25	27	28	30	26	28	272	304

Parameter Name	TBILocDuration1, TBILocDuration2, TBILocDuration3, TBILocDuration4, TBILocDuration5
CRF Field	TBILocDuration1, TBILocDuration2, TBILocDuration3, TBILocDuration4, TBILocDuration5
CRF Description	TBI Screen: Unconscious for how long: LOC Injury 1-5
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	HistTBI = History of previous TBI exposure (Q7B)
Variable Type	Text
Calculation Rule	
Permissible Range	Numerical?, ≥ or < 30 minutes?
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

TBI Screen: Unconscious for how long	TBILoc Duration1 (N)	TBILoc Duration2 (N)	TBILoc Duration3 (N)	TBILoc Duration4 (N)	TBILoc Duration5 (N)
N	140	35	13	9	5
< 30 minutes (including unknown)	105	27	10	8	4
≥ 30 minutes	34	7	2	1	0
Other responses	1	1	1	0	1
Missing/NA	459	564	586	590	594

Parameter Name	TBILocAge1, TBILocAge2, TBILocAge3, TBILocAge4, TBILocAge5
CRF Field	TBILocAge1, TBILocAge2, TBILocAge3, TBILocAge4, TBILocAge5
CRF Description	TBI Screen: Age at LOC Injury 1-5
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	HistTBI = History of previous TBI exposure (How old were you?)
Variable Type	Text
Calculation Rule	
Permissible Range	Numerical?, ≥ or < 15 years old?
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

TBI Screen: Age at LOC Injury	TBILocAge1 (N)	TBILocAge2 (N)	TBILocAge3 (N)	TBILocAge4 (N)	TBILocAge5 (N)
N	135	32	13	9	5
Numeric	105	16	5	2	1
Non-numeric	30	16	8	7	4
Missing/NA	464	567	586	590	594
Cleaned N	*135*	*29*	*12*	*8*	*4*
Mean	*26.70*	*25.29*	*27.71*	*24.56*	*30.5*
Median	*21*	*22.5*	*24.75*	*20.25*	*26*
Min	*3*	*5*	*13*	*15*	*18*
Max	*78*	*52*	*52*	*52*	*52*
SD	*16.97*	*12.87*	*13.08*	*12.27*	*15.18*

Parameter Name	TBILocOver5
CRF Field	If more than 5, how many more?
CRF Description	TBI Screen: # of KO over the 5 already listed
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	HistTBI = History of previous TBI exposure (If more than 5, how many more?)
Variable Type	Numerical?
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

TBI Screen: # of KO over the 5 already listed	Count (N)
N	6
Numerical	2
Non-numerical	3
Unknown	1
Missing/NA	593

Parameter Name	TBILocLongestKO
CRF Field	Longest period of unconsciousness?
CRF Description	TBI Screen: Longest period of unconsciousness?
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	HistTBI = History of previous TBI exposure (Longest knocked out?)
Variable Type	Numerical?
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

TBI Screen: Longest period of unconsciousness?	Count (N)
N	15
Numerical	5
Non-numerical	8
Unknown	2
Missing/NA	584

Parameter Name	TBILocOver30Min
CRF Field	How many ≥ 30 mins.?
CRF Description	TBI Screen: # of KO ≥ 30 mins
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	HistTBI = History of previous TBI exposure (How many ≥ 30 mins.?)
Variable Type	Numerical?
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

TBI Screen: # of KO ≥ 30 mins	Count (N)
N	6
Numerical	3
Non-numerical	1
Unknown	2
Missing/NA	593

Parameter Name	TBILocYoungestAge
CRF Field	Youngest age?
CRF Description	TBI Screen: Youngest age of KO
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	HistTBI = History of previous TBI exposure (Youngest age?)
Variable Type	Numerical?
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

TBI Screen: Youngest age of KO	Count (N)
N	10
Numerical	6
Non-numerical	2
Unknown	2
Missing/NA	589

Parameter Name	TBIDazedDuration1, TBIDazedDuration2, TBIDazedDuration3, TBIDazedDuration4, TBIDazedDuration5
CRF Field	TBIDazedDuration1, TBIDazedDuration2, TBIDazedDuration3, TBIDazedDuration4, TBIDazedDuration5
CRF Description	TBI Screen: Dazed & Confused for how long: Dazed Injury 1-5
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Text
Calculation Rule	
Permissible Range	Numerical?, ≥ or < 30 minutes?
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

TBI Screen: Dazed & Confused for how long: Dazed Injury	TBIDazed Duration1 (N)	TBIDazed Duration2 (N)	TBIDazed Duration3 (N)	TBIDazed Duration4 (N)	TBIDazed Duration5 (N)
N	93	19	4	1	0
< 30 minutes (including unknown)	58	12	3	0	0
≥ 30 minutes	35	7	1	1	0
Other responses	0	0	0	0	0
Missing/NA	506	580	595	598	599

Parameter Name	TBIDazedAge1, TBIDazedAge2, TBIDazedAge3, TBIDazedAge4, TBIDazedAge5
CRF Field	TBIDazedAge1, TBIDazedAge2, TBIDazedAge3, TBIDazedAge4, TBIDazedAge5
CRF Description	TBI Screen: Age at Dazed Injury1-5
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Text
Calculation Rule	
Permissible Range	Numerical?, ≥ or < 15 years old?
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

TBI Screen: Age at Dazed Injury	TBIDazedAge1 (N)	TBIDazedAge2 (N)	TBIDazedAge3 (N)	TBIDazedAge4 (N)	TBIDazedAge5 (N)
N	84	19	4	1	0
Numeric	68	13	3	0	0
Non-numeric	16	6	1	1	0
Missing/NA	515	580	595	598	599
Cleaned N	*84*	*19*	*4*	*1*	*0*
Mean	*28.49*	*30.16*			
Median	*23*	*24*			
Min	*5*	*9.5*			
Max	*74*	*55*			
SD	*16.93*	*14.63*			

Parameter Name	TBIDazedOver5
CRF Field	If more than 5, how many more?
CRF Description	TBI Screen: # of times dazed over the 5 already listed
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical?
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

TBI Screen: # of times dazed over the 5 already listed	Count (N)
N	2
Numerical	2
Non-numerical	0
Unknown	0
Missing/NA	597

Parameter Name	TBIDazedLongestKO
CRF Field	Longest period confused?
CRF Description	TBI Screen: Longest period of being dazed & confused?
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical?
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

TBI Screen: Longest period of being dazed & confused?	Count (N)
N	7
Numerical	2
Non-numerical	5
Unknown	0
Missing/NA	592

Parameter Name	TBIDazedOver30Min
CRF Field	How many ≥ 30 mins.?
CRF Description	TBI Screen: # of times dazed & confused ≥ 30 mins
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical?
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

TBI Screen: # of times dazed & confused ≥ 30 mins	Count (N)
N	2
Numerical	2
Non-numerical	0
Unknown	0
Missing/NA	597

Parameter Name	TBIDazedYoungestAge
CRF Field	Youngest age?
CRF Description	TBI Screen: Youngest age of dazed & confused injury
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical?
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

TBI Screen: Youngest age of dazed & confused injury	Count (N)
N	6
Numerical	5
Non-numerical	1
Unknown	0
Missing/NA	593

Parameter Name	TBIOverdose
CRF Field	TBIOverdose
CRF Description	TBI Screen Q9: Lost consciousness # of times from drug OD
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	HistTBI = History of previous TBI exposure (Q8)
Variable Type	Numerical?
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

TBI Screen Q9: Lost consciousness # of times from drug OD	Count (N)
N	254
Numerical	224
0	210
1-5	14
Non-numerical	30
None/No	3
888	14
Unknown	9
Other responses	3
Missing/NA	345

Parameter Name	TBIChocked
CRF Field	TBIChocked
CRF Description	TBI Screen Q9: Lost consciousness # of times from being choked
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	HistTBI = History of previous TBI exposure (Q8)
Variable Type	Numerical?
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

TBI Screen Q9: Lost consciousness # of times from being choked	Count (N)
N	251
Numerical	223
0	207
1-6	16
Non-numerical	28
None/No	3
888	13
Unknown	9
Other responses	3
Missing/NA	348

Parameter Name	EDIntubation
CRF Field	Intubated in ED
CRF Description	Was the patient intubated in the ED?
CRF Input Type	Radio button
NIND 2.0 CDE ID	C01500
NIND 2.0 CDE Name	Airway treatment type
IMPACT 1.5 CDE	ERAir = Emergency Tx airway support
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	CDEs are not ED specific.

Intubated in ED	Count (N)
Y – Yes	59
N – No	537
Missing/NA	3

Parameter Name	EDArrSBP, EDDischSBP
CRF Field	SBP
CRF Description	Systolic blood pressure @ ED arrival, Systolic blood pressure @ ED Discharge
CRF Input Type	Text area
NIND 2.0 CDE ID	C01565
NIND 2.0 CDE Name	Blood pressure systolic measurement
IMPACT 1.5 CDE	SBP = Systolic Blood Pressure
Variable Type	Numerical
Calculation Rule	
Permissible Range	30-300 (integer)
Recommended Interpretation for missing/NA values	Unknown/Not reported, Not done
Comments	

SBP	ED arrival (mmHg)	ED discharge (mmHg)
N	587	562
Mean	140.72	130.10
Median	138	128
Min	48	72
Max	240	215
SD	26.72	20.77
Out of range (0, 888, 999)	12	37
Missing/NA	0	0

Parameter Name	EDArrDBP, EDDischDBP
CRF Field	DBP
CRF Description	Diastolic blood pressure @ ED arrival, Diastolic blood pressure @ ED discharge
CRF Input Type	Text area
NIND 2.0 CDE ID	C01507
NIND 2.0 CDE Name	Blood pressure diastolic measurement
IMPACT 1.5 CDE	DBP = Diastolic Blood Pressure
Variable Type	Numerical
Calculation Rule	
Permissible Range	5-200 (integer)
Recommended Interpretation for missing/NA values	Unknown/Not reported, Not done
Comments	

DBP	ED arrival (mmHg)	ED discharge (mmHg)
N	490	553
Mean	82.46	72.78
Median	82	72
Min	8	18
Max	147	149
SD	18.80	14.53
Out of range (0, 888, 999)	109	46
Missing/NA	0	0

Hospital	Emergency Department	HR

Parameter Name	EDArrHR, EDDischHR
CRF Field	HR
CRF Description	Heart rate @ ED arrival, Heart rate @ ED Discharge
CRF Input Type	Text area
NIND 2.0 CDE ID	C01521
NIND 2.0 CDE Name	Heart rate
IMPACT 1.5 CDE	HR = Heart Rate
Variable Type	Numerical
Calculation Rule	
Permissible Range	5-200 (integer)
Recommended Interpretation for missing/NA values	Unknown/Not reported, Not done
Comments	

HR	ED arrival (beats per min)	ED discharge (beats per min)
N	588	562
Mean	88.61	82.53
Median	87	81.5
Min	14	43
Max	155	164
SD	19.47	15.95
Out of range (0, 888, 999)	11	37
Missing/NA	0	0

Parameter Name	EDArrRespRate, EDDischRespRate
CRF Field	RR
CRF Description	Respiratory rate @ ED arrival, Respiratory rate @ ED discharge
CRF Input Type	Text area
NIND 2.0 CDE ID	C01535
NIND 2.0 CDE Name	Respiratory rate
IMPACT 1.5 CDE	RespRate = Respiratory Rate
Variable Type	Numerical
Calculation Rule	
Permissible Range	1-100 (integer)
Recommended Interpretation for missing/NA values	Unknown/Not reported, Not done
Comments	

RR	ED arrival (breaths per min)	ED discharge (breaths per min)
N	573	549
Mean	17.51	17.40
Median	17	16
Min	6	9
Max	74	107
SD	4.22	6.81
Out of range (0, 888, 999)	26	50
Missing/NA	0	0

Parameter Name	EDArrRespRateType, EDDischRespRateType
CRF Field	Ventilation:
CRF Description	Type of ventilation @ ED arrival, Type of ventilation @ ED discharge
CRF Input Type	Dropdown
NIND 2.0 CDE ID	C01551
NIND 2.0 CDE Name	Respiration type
IMPACT 1.5 CDE	AdmABC = ABC Status on arrival to study hospital
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Others, Unknown/Not reported
Comments	

Ventilation	ED arrival (N)	ED discharge (N)
1 - Spontaneous	530	487
2 - Assisted	63	91
Missing/NA	6	21

Parameter Name	EDArrTemp, EDDischTemp
CRF Field	Temp, °C
CRF Description	Temperature @ ED arrival in Celcius, Temperature @ ED Discharge in Celcius
CRF Input Type	Text area
NIND 2.0 CDE ID	C01539
NIND 2.0 CDE Name	Temperature measurement
IMPACT 1.5 CDE	Temp = Temperature
Variable Type	Numerical
Calculation Rule	
Permissible Range	30-50
Recommended Interpretation for missing/NA values	Unknown/Not reported, Not done
Comments	

Temp	ED arrival (°C)	ED discharge (°C)
N	373	193
Mean	36.38	36.58
Median	36.6	36.7
Min	16.8	32.3
Max	38.5	38.2
SD	1.35	0.70
Out of range (97-99.2)	8	3
Out of range (99.9)	4	14
Out of range (0, 888, 999)	222	392
Missing/NA	0	0

Hospital	Emergency Department	SpO2

Parameter Name	EDArrSpO2, EDDischSpO2
CRF Field	SpO2
CRF Description	SpO2 @ ED arrival, SpO2 @ ED discharge
CRF Input Type	Text area
NIND 2.0 CDE ID	C01554
NIND 2.0 CDE Name	Oxygen saturation measurement
IMPACT 1.5 CDE	SaO2 = Oxygen Saturation
Variable Type	Numerical
Calculation Rule	
Permissible Range	75-100
Recommended Interpretation for missing/NA values	Unknown/Not reported, Not done
Comments	

SpO2	ED arrival (%)	ED discharge (%)
N	566	531
Mean	98.43	98.54
Median	99	99
Min	85	19
Max	100	100
SD	2.10	3.80
Out of range (0, 888, 999)	33	68
Out of range (others)	1	0
Missing/NA	0	0

Parameter Name	GcsEDArrAssmtStat, GcsEDDischAssmtStat
CRF Field	ED Arrival GCS Assmt Complete, ED Disch GCS Assmt Complete
CRF Description	
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

GCS Assmt Complete	ED arrival (N)	ED discharge (N)
1 - Complete	570	531
2 - Not Done	5	39
3 - Not Found	0	1
Missing/NA	24	28

Parameter Name	GcsEDArrTimeOfTest
CRF Field	Time of Assessment:
CRF Description	Time of GCS test @ ED arrival
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Time of Assessment	ED arrival (N)
1 - ED Admission	580
2 - Post-stabilization	5
Missing/NA	24

Parameter Name	GcsEDArrScoreTimeSinceInj, GcsEDDischScoreTimeSinceInj
CRF Field	Time Since Injury (GCS @ ED Arrival), Time Since Injury (GCS @ ED Discharge)
CRF Description	Time Since Injury (GCS @ ED Arrival), Time Since Injury (GCS @ ED Discharge)
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Date & Time of GCS Assessment – Date & Time of Injury
Permissible Range	> 0
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	

Time Since Injury (GCS Assmt)	ED arrival (hours)	ED discharge (hours)
N	575	539
Mean	152.57	175.44
Median	0.95	5.75
Min	-0.33	0.17
Max	78889.4	87577.5
SD	3303.31	3777.31
Out of range	5	9
Missing/NA	19	51

Parameter Name	GcsEDArrAssmtCond, GcsEDDischAssmtCond, *GcsEDArrAssmtCondOther, GcsEDDischAssmtCondOther*
CRF Field	Assessment Conditions
CRF Description	GCS Assessment conditions @ ED arrival, GCS Assessment conditions @ ED discharge
CRF Input Type	Dropdown, *Text area*
NIND 2.0 CDE ID	C01007
NIND 2.0 CDE Name	Sedation status
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Others conditions, Unknown/Not reported
Comments	"paralyzed and sedated" is recorded 3 different ways

Assessment Conditions	ED arrival (N)	ED discharge (N)
1 - Sedated	23	113
2 - Paralyzed	19	29
3 - No sedation or Paralysis	533	407
4 - Other	9	9
Missing/NA	9	41
Specify Other Assmt Condition	*89*	*84*

Parameter Name	GcsEDArrPupils, GcsEDDischPupils
CRF Field	Pupillary reactivity:
CRF Description	GCS Pupillary reactivity @ ED arrival, GCS Pupillary reactivity @ ED discharge
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	Pup_Adm = Pupils admission to study hospital , Pup_Disch = Pupils discharge
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Pupillary reactivity	ED arrival (N)	ED discharge (N)
1 - Both pupils reactive	480	279
2 - One non-reacting pupil	9	6
3 - Both pupils non-reactive	16	10
0 - ED Arrival Pupils Not Done	82	249
Missing/NA	12	55

Parameter Name	GcsEDPupilSizeR, GcsEDDischPupilSizeR
CRF Field	Right Pupil Size
CRF Description	Right pupil size @ED arrival, Right pupil size @ ED discharge
CRF Input Type	Dropdown
NIND 2.0 CDE ID	C01005
NIND 2.0 CDE Name	Pupil right eye measurement
IMPACT 1.5 CDE	Size
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Right Pupil Size (mm)	ED arrival (N)	ED discharge (N)
1	14	3
2	105	43
3	149	82
4	69	33
5	25	8
6	12	5
7	2	1
8	1	0
Missing/NA	222	424

Parameter Name	GcsEDArrPupilReactR, GcsEDDischPupilReactR
CRF Field	Rt Pupil Reactivity
CRF Description	
CRF Input Type	Dropdown
NIND 2.0 CDE ID	C01003
NIND 2.0 CDE Name	Pupil reactivity to light right eye result
IMPACT 1.5 CDE	Reactivity
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Rt Pupil Reactivity	ED arrival (N)	ED discharge (N)
1 - Yes	137	26
0 - No	5	0
Missing/NA	457	573

Parameter Name	GcsEDPupilSizeL, GcsEDDischPupilSizeL
CRF Field	Left Pupil Size
CRF Description	Left pupil size @ED arrival, Left pupil size @ ED discharge
CRF Input Type	Dropdown
NIND 2.0 CDE ID	C01006
NIND 2.0 CDE Name	Pupil left eye measurement
IMPACT 1.5 CDE	Size
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Right Pupil Size (mm)	ED arrival (N)	ED discharge (N)
1	17	3
2	110	43
3	144	82
4	71	35
5	25	7
6	8	3
7	1	0
8	1	0
Missing/NA	222	426

Parameter Name	GcsEDArrPupilReactL, GcsEDDischPupilReactL
CRF Field	Lt Pupil Reactivity
CRF Description	
CRF Input Type	Dropdown
NIND 2.0 CDE ID	C01004
NIND 2.0 CDE Name	Pupil reactivity to light left eye result
IMPACT 1.5 CDE	Reactivity
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Rt Pupil Reactivity	ED arrival (N)	ED discharge (N)
1 - Yes	71	12
0 - No	3	1
Missing/NA	525	586

Parameter Name	GcsEDArrEyes, GcsEDDischEyes, *GcsEDArrEyesUntestable, GcsEDDischEyesUntestable*
CRF Field	Eye Opening
CRF Description	GCS Eye value @ ED arrival, GCS Eye value @ ED discharge
CRF Input Type	Dropdown, *Checkbox*
NIND 2.0 CDE ID	C01000
NIND 2.0 CDE Name	GCS Eye response
IMPACT 1.5 CDE	Eye opening
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Untestable, Not applicable/Not done, Unknown/Not reported
Comments	

Eye Opening	ED arrival (N)	ED discharge (N)
1 - No Response	62	63
2 - To Pain	14	3
3 - To Verbal Command	22	23
4 - Spontaneously	487	445
Missing/NA	14	65
Eyes Untestable	*7*	*25*

Parameter Name	GcsEDArrVerbal, GcsEDDischVerbal, *GcsEDArrVerbalUntestable, GcsEDDischVerbalUntestable*
CRF Field	Best Verbal Response
CRF Description	GCS verbal value @ ED arrival, GCS verbal value @ ED discharge
CRF Input Type	Dropdown, *Checkbox*
NIND 2.0 CDE ID	C01002
NIND 2.0 CDE Name	GCS Verbal response
IMPACT 1.5 CDE	Verbal
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Untestable, Not applicable/Not done, Unknown/Not reported
Comments	

Best Verbal Response	ED arrival (N)	ED discharge (N)
1 - No Response	38	39
2 - Incomprehensible Sounds	17	1
3 - Inappropriate Words	12	2
4 - Disoriented & Converses	118	40
5 - Oriented & Converses	376	422
Missing/NA	38	95
Verbal Untestable	*31*	*55*

Parameter Name	GcsEDArrMotor, GcsEDDischMotor, *GcsEDArrMotorUntestable, GcsEDDischMotorUntestable*
CRF Field	Best Motor Response
CRF Description	GCS motor value @ ED arrival, GCS motor value @ ED discharge
CRF Input Type	Dropdown, *Checkbox*
NIND 2.0 CDE ID	C01001
NIND 2.0 CDE Name	GCS Motor response
IMPACT 1.5 CDE	Motor
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Untestable, Not applicable/Not done, Unknown/Not reported
Comments	

Best Motor Response	ED arrival (N)	ED discharge (N)
1 - No Response	32	39
2 - Extension	2	0
3 - Flexion Abnormal	6	4
4 - Flexion Withdrawal	8	6
5 - Localizes to Pain	27	11
6 - Obeys Commands	500	467
Missing/NA	24	72
Motor Untestable	*17*	*32*

Parameter Name	GcsEDArrScore, GcsEDDischScore, *GcsEDArrScoreUntestable, GcsEDDischScoreUntestable*
CRF Field	GCS Total
CRF Description	GCS total score @ ED arrival (auto calculated), GCS total score @ ED discharge (auto calculated)
CRF Input Type	Text area, *Checkbox*
NIND 2.0 CDE ID	C01016
NIND 2.0 CDE Name	GCS Total score (not time specific)
IMPACT 1.5 CDE	GCS_Adm = GCS admission to study hospital , GCS_Disch = GCS discharge
Variable Type	Numerical
Calculation Rule	
Permissible Range	3-15 (integer)
Recommended Interpretation for missing/NA values	Not reported
Comments	

GCS Total	Prehospital	ED Arrival	ED Discharge
N	491	561	504
Mean	13.21	13.76	14.03
Median	15	15	15
Min	3	3	3
Max	15	15	15
SD	3.19	2.85	2.92
Out of range (999 – Not found)	4	0	0
Out of range (non-numerical)	1	0	0
Out of range (0)	0	38	95
Missing/NA	103	0	0
1 or more components untestable	89	38	95

Parameter Name	EDWbc, *EDWbcSI, EDWbcNotDone*
CRF Field	Results, *Specify if Other, NotDone*
CRF Description	ED: Value of White blood cell test in X10^9/L or X10^3/uL, *ED: Placeholder for White blood cell test in SI Units, ED: White blood cell test not done (checkbox)*
CRF Input Type	Text area, *Text area, Checkbox*
NIND 2.0 CDE ID	C01705
NIND 2.0 CDE Name	Lab test name: White Blood Cell Count (WBC)
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	0.1-50
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

White blood cell	10^9/L or 10^3/uL	SI Unit
N	431	
Mean	11.30	
Median	10.4	
Min	1.8	
Max	33.5	
SD	5.19	
Missing/NA	168	
Not Done	160	

Parameter Name	EDHemoglobin, *EDHemoglobinSI, EDHemoglobinNotDone*
CRF Field	EDHemoglobin, *EDHemoglobinOtherUnitsSpecify, EDHemoglobinNotDone*
CRF Description	ED: Value of Hemoglobin test in g/dL, *ED: Value of Hemoglobin test in mmol/L (SI unit) (EDHemoglobin x 0.6206), ED: Hemoglobin test not done (checkbox)*
CRF Input Type	Text area, *Text area, Checkbox*
NIND 2.0 CDE ID	C01705
NIND 2.0 CDE Name	Lab test name: Hemoglobin (HB)
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	0.1-50
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Hemoglobin	g/dL	mmol/L
N	472	450
Mean	13.94	8.66
Median	14	8.75
Min	4.94	3.07
Max	46	28.55
SD	2.78	1.74
Out of range (0)	0	148
Missing/NA	127	1
Not Done	126	

Hospital > Emergency Department (3) > Hematocrit

Parameter Name	EDHematocrit, *EDHematocritSI, EDHemoglobinNotDone*
CRF Field	EDHematocrit, *EDHematocritOtherUnitsSpecify, EDHemoglobinNotDone*
CRF Description	ED: Value of Hematocrit test in %, *ED: Placeholder for Hematocrit test in SI Units, ED: Hematocrit test not done (checkbox)*
CRF Input Type	Text area, *Text area, Checkbox*
NIND 2.0 CDE ID	C01705
NIND 2.0 CDE Name	Lab test name: Hematocrit (HCT)
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	1-300
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Hematocrit	%	SI Units
N	458	
Mean	41.48	
Median	41.1	
Min	15.7	
Max	221	
SD	12.36	
Missing/NA	141	
Not Done	137	

Parameter Name	EDPlatelet, *EDPlateletSI, EDPlateletNotDone*
CRF Field	EDPlatelet, *EDPlateletOtherUnitsSpecify, EDPlateletNotDone*
CRF Description	ED: Value of Platelet test in X10^9/L or X10^3/uL, *ED: Placeholder for Platelet test in SI Units, ED: Platelet test not done (checkbox)*
CRF Input Type	Text area, *Text area, Checkbox*
NIND 2.0 CDE ID	C01705
NIND 2.0 CDE Name	Lab test name: Platelet Count
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	1-1000
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Platelet	10^9/L or 10^3/uL	SI Units
N	454	
Mean	249.15	
Median	240	
Min	22	
Max	533	
SD	83.87	
Missing/NA	145	
Not Done	138	

Parameter Name	EDOsmo, *EDOsmoSI, EDOsmoNotDOne*
CRF Field	EDOsmo, *EDOsmoOtherUnitsSpecify, EDOsmoNotDOne*
CRF Description	ED: Value of Osmolality test in mOsm/kg, *ED: Placeholder for Osmolality test in SI Units, ED: Osmolality test not done (checkbox)*
CRF Input Type	Text area, *Text area, Checkbox*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	1-1000
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Osmolality	mOsm/kg	SI Units
N	33	
Mean	312.91	
Median	300	
Min	197	
Max	392	
SD	0.12	
Missing/NA	566	
Not Done	508	

Parameter Name	EDInr, *EDInrNotDone*
CRF Field	EDInr, *EDInrNotDone*
CRF Description	ED: Value of INR test (No units), *ED: INR test not done (checkbox)*
CRF Input Type	Text area, *Text area, Checkbox*
NIND 2.0 CDE ID	C01705
NIND 2.0 CDE Name	Lab test name: International Normalized Ratio (INR)
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	0.1-50
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

INR	(no unit)
N	403
Mean	1.26
Median	1.1
Min	0.8
Max	25.2
SD	1.43
Missing/NA	196
Not Done	184

Parameter Name	EDProthrombineTime, *EDProthrombineTimeSI, EDProthrombineTimeNotDone*
CRF Field	EDProthrombineTime, *EDProthrombineTimeOtherUnitsSpecify, EDProthrombineTimeNotDone*
CRF Description	ED: Value of Prothrombin time (PT) test in sec., *ED: Placeholder for Prothrombin time (PT) test in SI Units, ED: Prothrombin time (PT) test not done (checkbox)*
CRF Input Type	Text area, *Text area, Checkbox*
NIND 2.0 CDE ID	C01705
NIND 2.0 CDE Name	Lab test name: Prothrombine Time (PTT)
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	0.1-200
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Prothrombin time	seconds	SI Units
N	402	
Mean	14.42	
Median	13.7	
Min	1	
Max	60.6	
SD	4.23	
Missing/NA	197	
Not Done	185	

Parameter Name	EDaPtt, *EDaPttSI, EDaPttNotDone*
CRF Field	EDaPtt, *EDaPttOtherUnitsSpecify, EDaPttNotDone*
CRF Description	ED: Value of aPTT test in Seconds, *ED: Placeholder for aPTT test in SI Units, ED: aPTT test not done (checkbox)*
CRF Input Type	Text area, *Text area, Checkbox*
NIND 2.0 CDE ID	C01705
NIND 2.0 CDE Name	Lab test name: Activated Partial Thromboplastin Time (aPTT)
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	0.1-500
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

aPTT	seconds	SI Units
N	380	
Mean	28.86	
Median	27.15	
Min	0.9	
Max	260	
SD	15.10	
Missing/NA	219	
Not Done	206	

Parameter Name	EDSodium, *EDSodiumSI, EDSodiumNotDone*
CRF Field	EDSodium, *EDSodiumOtherUnitsSpecify, EDSodiumNotDone*
CRF Description	ED: Value of Sodium test in mmol/L or mEq/L, *ED: Placeholder for Sodium test in SI Units, ED: Sodium test not done (checkbox)*
CRF Input Type	Text area, *Text area, Checkbox*
NIND 2.0 CDE ID	C01705
NIND 2.0 CDE Name	Lab test name: Sodium (Na)
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	0.1-300
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Sodium	mmol/L or mEq/L	SI Units
N	451	
Mean	139.36	
Median	140	
Min	13.9	
Max	149	
SD	6.71	
Missing/NA	148	
Not Done	144	

Parameter Name	EDPotassium, *EDPotasiumSI, EDPotasiumNotDone*
CRF Field	EDPotassium, *EDPotasiumOtherUnitsSpecify, EDPotasiumNotDone*
CRF Description	ED: Value of Potassium test in mmol/L or mEq/L, *ED: Placeholder for Potassium test in SI Units, ED: Potassium test not done (checkbox)*
CRF Input Type	Text area, *Text area, Checkbox*
NIND 2.0 CDE ID	C01705
NIND 2.0 CDE Name	Lab test name: Potassium (K)
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	0.1-100
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Potassium	mmol/L or mEq/L	SI Units
N	447	
Mean	4.15	
Median	3.9	
Min	1.1	
Max	43	
SD	3.00	
Out of range (non-numeric)	1	
Missing/NA	151	
Not Done	147	

Parameter Name	EDChloride, *EDChlorideSI, EDChlorideNotDone*
CRF Field	EDChloride, *EDChlorideOtherUnitsSpecify, EDChlorideNotDone*
CRF Description	ED: Value of Chloride test in mmol/L or mEq/L, *ED: Placeholder for Chloride test in SI Units, ED: Chloride test not done (checkbox)*
CRF Input Type	Text area, *Text area, Checkbox*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	0.1-300
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Chloride	mmol/L or mEq/L	SI Units
N	448	
Mean	105.31	
Median	106	
Min	1.9	
Max	131	
SD	6.45	
Missing/NA	151	
Not Done	145	

Parameter Name	EDCO2, *EDCO2SI, EDCO2NotDone*
CRF Field	EDCO2, *EDCO2OtherUnitsSpecify, EDCO2NotDone*
CRF Description	ED: Value of CO2 test in mmol/L or mEq/L, *ED: Placeholder for CO2 test in SI Units, ED: CO2 test not done (checkbox)*
CRF Input Type	Text area, *Text area, Checkbox*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	1-200
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

CO2	mmol/L or mEq/L	SI Units
N	364	
Mean	25.06	
Median	25	
Min	9	
Max	72	
SD	4.24	
Missing/NA	235	
Not Done	184	

Parameter Name	EDGlucose, *EDGlucoseSI, EDGlucoseNotDone*
CRF Field	EDGlucose, *EDGlucoseOtherUnitsSpecify, EDGlucoseNotDone*
CRF Description	ED: Value of Glucose test in mg/dL, *ED: Value of Glucose test in mmol/L (SI unit) (EDGlucose x 0.555), ED: Glucose test not done (checkbox)*
CRF Input Type	Text area, *Text area, Checkbox*
NIND 2.0 CDE ID	C01705
NIND 2.0 CDE Name	Lab test name: Glucose
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	0.1-1000
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Glucose	mg/dL	mmol/L
N	466	446
Mean	129.08	71.41
Median	117.5	64.94
Min	42	23.31
Max	462	256.41
SD	47.71	25.59
Out of range (0)	0	152
Missing/NA	133	1
Not Done	130	

Parameter Name	EDCreatinine, *EDCreatinineSI, EDCreatinineNotDone*
CRF Field	EDCreatinine, *EDCreatinineOtherUnitsSpecify, EDCreatinineNotDone*
CRF Description	ED: Value of Creatinine test in mg/dL, *ED: Value of Creatinine test in umol/L (SI unit) (EDCreatinine x 76.26), ED: Creatinine test not done (checkbox)*
CRF Input Type	Text area, *Text area, Checkbox*
NIND 2.0 CDE ID	C01705
NIND 2.0 CDE Name	Lab test name: Creatinine
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	0.1-50
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Creatinine	mg/dL	umol/L
N	463	442
Mean	0.94	71.88
Median	0.89	67.87
Min	0.15	11.44
Max	8.5	648.21
SD	0.59	45.74
Out of range (0)	0	156
Missing/NA	136	1
Not Done	135	

Parameter Name	EDBun, *EDBunSI, EDBunNotDone*
CRF Field	EDBun, *EDBunOtherUnitsSpecify, EDBunNotDone*
CRF Description	ED: Blood Urea Nitrogen (BUN) test in mg/dL, *ED: Value of BUN in mmol/L (of Urea) (EDBun x 0.357), ED: BUN test not done (checkbox)*
CRF Input Type	Text area, *Text area, Checkbox*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	1-200
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Blood Urea Nitrogen (BUN)	mg/dL	mmol/L
N	410	390
Mean	15.23	5.42
Median	13	4.64
Min	3	1.07
Max	109	38.91
SD	9.57	3.45
Out of range (0, non-numeric)	1	207
Missing/NA	188	2
Not Done	183	

Parameter Name	EDLactate, *EDLactateSI, EDLactateNotDone*
CRF Field	EDLactate, *EDLactateOtherUnitsSpecify, EDLactateNotDone*
CRF Description	ED: Value of Lactate test in mg/dL, *ED: Value of Lactate test in mmol/L (SI unit) (EDLactate x 0.111), ED: Lactate test not done (checkbox)*
CRF Input Type	Text area, *Text area, Checkbox*
NIND 2.0 CDE ID	C01705
NIND 2.0 CDE Name	Lab test name: Lactate Dehydrogenase (LDH)
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	0.1-1000
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Lactate	mg/dL	mmol/L
N	64	57
Mean	2.77	0.30
Median	2.45	0.27
Min	0.7	0.08
Max	8.7	0.97
SD	1.61	0.19
Out of range (0)	0	540
Missing/NA	535	2
Not Done	490	

Parameter Name	EDDrugScreenSampleType, *EDDrugScreenUnk*
CRF Field	Type of sample, *Unknown/not done*
CRF Description	Type of sample used for toxic drug screen in ED, *Toxic drug screen unknown/not done in ED*
CRF Input Type	Radio button, *Checkbox*
NIND 2.0 CDE ID	C01719
NIND 2.0 CDE Name	Drug screen sample type
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Drug Screen Type of sample	Count (N)
1 - Serum	131
2 - Urine	93
Missing/NA	375
Unknown/not done	*164*

Parameter Name	EDDrugScreenNone, EDDrugScreenOpioids, EDDrugScreenBenzo, EDDrugScreenCannabis, EDDrugScreenAmph, EDDrugScreenCocaine, EDDrugScreenBarb, EDDrugScreenPCP, EDDrugScreenMethadone, EDDrugScreenOther, *EDDrugScreenOtherTxt, EDDrugScreenUnk*
CRF Field	None, Opioids, Benzodiazepines, Cannabis, Amphetamines, Cocaine, Barbiturates, PCP, Methadone, Other, *EDDrugScreenOtherTxt, Unknown/not done*
CRF Description	No toxic drug screen performed in ED, Drug test in ED for Opioids, Drug test in ED for Benzodiazepines, Drug test in ED for Cannabis, Drug test in ED for Amphetamines, Drug test in ED for Cocaine, Drug test in ED for Barbiturates, Drug test in ED for PCP, Drug test in ED for Methadone, Drug test in ED for other drug, *Drug test in ED for other drug: Name of drug, Toxic drug screen unknown/not done in ED*
CRF Input Type	Checkboxes, *Text area*
NIND 2.0 CDE ID	C01718
NIND 2.0 CDE Name	Drug screen positive substance type
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Drug Screen Result	Original (N)	Clean (N)
None	109	109
Opioids	19	20
Benzodiazepines	29	29
Cannabis	7	7
Amphetamines	13	13
Cocaine	9	9
Barbiturates	2	2
PCP	0	0
Methadone	2	2
Other	4	3
Name of other drug	*13*	*3*
Unknown/not done	*164*	*164*

Parameter Name	EDDrugScreenAlcoholDone
CRF Field	Blood Alcohol Done
CRF Description	
CRF Input Type	Radio button
NIND 2.0 CDE ID	C01715
NIND 2.0 CDE Name	Alcohol blood test performed indicator
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Blood Alcohol Done	Count (N)
1 – Yes	232
0 - No	351
Missing/NA	16

Parameter Name	EDDrugScreenAlcohol
CRF Field	Blood Alcohol Level
CRF Description	Blood Alcohol level in ED (mg/100ml blood)
CRF Input Type	Text area
NIND 2.0 CDE ID	C01716
NIND 2.0 CDE Name	Alcohol blood level measurement
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	0-700
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Blood Alcohol Level	mg/100ml blood
N	284
Mean	89.65
Median	0
Min	0
Max	506
SD	117.11
Out of range (non-numeric)	1
Missing/NA	314

Parameter Name	EDPregTestDone
CRF Field	Pregnancy Test Done
CRF Description	
CRF Input Type	Radio button
NIND 2.0 CDE ID	C01702
NIND 2.0 CDE Name	Pregnancy test date and time
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Pregnancy Test Done	Count (N)
1 – Yes	35
0 - No	550
Missing/NA	14

Parameter Name	EDPregTestSampleType
CRF Field	Type of sample
CRF Description	Type of sample used for pregnancy test in ED
CRF Input Type	Radio button
NIND 2.0 CDE ID	C01704
NIND 2.0 CDE Name	Pregnancy test specimen type
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Pregnancy Test Type of sample	Count (N)
1 – Serum	14
2 - Urine	23
Missing/NA	562

Parameter Name	EDPregTest
CRF Field	Result:
CRF Description	Result of pregnancy test in ED
CRF Input Type	Radio button
NIND 2.0 CDE ID	C01710
NIND 2.0 CDE Name	Pregnancy test qualitative result
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Pregnancy Test Result	Count (N)
1 – Positive	0
0 - Negative	52
Missing/NA	547

Parameter Name	EDIVCrystalloids, EDIVSaline, EDIVBlood, EDIVAlbumin, EDIVVasopressors, EDIVMannitol, EDIVNone
CRF Field	Crystalloids, Hypertonic saline, Blood, Albumin, Vasopressors, Mannitol, None
CRF Description	IV fluids in ED: Crystalloids, IV fluids in ED: Saline, IV fluids in ED: Blood, IV fluids in ED: Albumin, IV fluids in ED: Vasopressors, IV fluids in ED: Mannitol, IV fluids in ED: None
CRF Input Type	Checkboxes
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	IV fluids – Crystalloids, IV fluids - Hypertonic saline, IV fluids – Blood, Vasopressors, No specific therapy
IMPACT 1.5 CDE	IV fluids – Crystalloids, IV fluids - Hypertonic saline, IV fluids – Blood, Vasopressors, No specific treatment
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

IV fluids in ED	Count (N)
Crystalloids	379
Hypertonic saline	2
Blood	29
Albumin	0
Vasopressors	0
Mannitol	9
None	189

Parameter Name	EDAbgDone
CRF Field	ED ABG Completion
CRF Description	
CRF Input Type	Radio button
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

ED ABG Completion	Count (N)
1 – Yes	85
0 - No	479
Missing/NA	35

Parameter Name	EDAbgPH, EDAbgPaCO2, EDAbgPaO2, EDAbgBicarbonate, EDAbgBe, EDAbgBd, EDAbgFiO2, *EDAbgFiO2Unk*
CRF Field	pH, pCO2, paO2, HCO3, Bd/Be, BD, FiO2, *FiO2 Unknown*
CRF Description	First Arterial Blood Gas (ABG) in ED: pH, First Arterial Blood Gas (ABG) in ED: PaCO2(mm Hg), First Arterial Blood Gas (ABG) in ED: PaO2 (mm Hg), First arterial blood gas in ED: HCO3 (mmol/L), First Arterial Blood Gas (ABG) in ED: BE (mmol/L or mEq/L), ED: Value of BD (base deficit) test in mmol/L or mEq/L, First Arterial Blood Gas (ABG) in ED: FiO2 (fraction of inspired oxygen) (%), First arterial blood gas in ED FiO2 unknown (checkbox)
CRF Input Type	Text area, *Checkbox*
NIND 2.0 CDE ID	C01559, C01560
NIND 2.0 CDE Name	Partial pressure carbon dioxide arterial measurement, Partial pressure oxygen arterial measurement
IMPACT 1.5 CDE	pH = Arterial pH, PaCO2 = Arterial PaCO2 , PaO2 = Arterial PaO2
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

First Arterial Blood Gas (ABG) in ED	pH	pCO2 (mmHg)	paO2 (mmHg)	HCO3 (mmol/L)	Bd/Be (mmol/L or mEq/L)	BD (mmol/L or mEq/L)	FiO2 (%)
N	87	143	85	86	42	46	12
Mean	7.34	31.98	39.86	22.42	2.45	3.68	24.56
Median	7.4	27	36	23	2	3	10
Min	7	12	2	11.6	-18.4	-4	0.2
Max	7.6	74.5	98	38	16	16	90
SD	0.09	10.33	23.38	0.17	5.05	3.54	32.63
Out of range (0, 888, 99, 99.9, 999)	512	1	3	3	5	5	6
Out of range (non-numeric)	0	0	0	0	0	0	2
Missing/NA	0	455	511	510	552	548	579
FiO2 Unknown							*73*

Parameter Name	EDAbgCond
CRF Field	Conditions:
CRF Description	Conditions of first ABG in ED
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	

Conditions of first ABG in ED	Count (N)
1 – Preintubation, Room Air	12
2 - Preintubation O2	2
3 - Postintubation	52
4 - Unknown	11
Missing/NA	522

Parameter Name	EDComplEventAsp, EDComplEventCardArr, EDComplEventSeizures, EDComplEventHypotension, EDComplEventHypoxia
CRF Field	Aspiration, Cardiopulmonary arrest, Seizures, Hypotension, Hypoxia
CRF Description	Complicating event in ED: Aspiration, Complicating event in ED: Cardiopulmonary arrest, Complicating event in ED: Seizures, ED: Complicating Events: Hypotension, ED: Complicating Events: Hypoxia,
CRF Input Type	Radio button
NIND 2.0 CDE ID	C05465, C05459, C05460, C05453, C05457
NIND 2.0 CDE Name	Aspiration indicator, Cardiac arrest indicator, Seizure indicator, Hypotensive episode indicator, Hypoxic episode indicator
IMPACT 1.5 CDE	SSIClin-Seiz = Seizures during clinical course, SISClin-Hypotens = Hypotensive episode during clinical course, SISClin-Hypox = Hypoxic episode during clinical course
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Complicating event in ED	Aspiration (N)	Cardiopulmonary arrest (N)	Seizures (N)	Hypotension (N)	Hypoxia (N)
1 – Yes	7	0	5	25	28
0 - No	558	594	586	566	564
2 – Unknown (only Aspiration)	29				
Missing/NA	5	5	8	8	7

Parameter Name	EDDischTimeSinceInj
CRF Field	Time Since Injury (ED discharge)
CRF Description	Time Since Injury (ED discharge)
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Date & Time of ED Discharge– Date & Time of Injury
Permissible Range	> 0
Recommended Interpretation for missing/NA values	Expired, Unknown/Not reported
Comments	Only

Time Since Injury (ED discharge)	Time (hours)
N	586
Mean	21.23
Median	6.26
Min	0.62
Max	7281
SD	301.13
Out of range	6
Missing/NA	7

Parameter Name	DispER
CRF Field	Destination
CRF Description	Disposition from ED
CRF Input Type	Dropdown
NIND 2.0 CDE ID	C04803
NIND 2.0 CDE Name	Emergency room discharge destination type
IMPACT 1.5 CDE	DispER = Discharge destination from the emergency room
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	

Destination	Count (N)
1 – Discharge home	173
2 - Transferred other facility	0
3 - Hospital admission--Ward	114
4 - Hospital admission--Stepdown Unit	93
5 - Hospital admission--ICU	178
6 - Hospital admission--Operating room	38
7 - Expired	0
Missing/NA	3

Parameter Name	DNRWrittenTimeSinceInj
CRF Field	Time Since Injury (DNR)
CRF Description	Time Since Injury (DNR)
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Date & Time of DNR Written– Date & Time of Injury
Permissible Range	> 0
Recommended Interpretation for missing/NA values	Expired, Not applicable/Not done, Unknown/Not reported
Comments	Hospital records available for 428 patients

Time Since Injury (DNR)	Time (hours)
N	5
Mean	300.51
Median	372.1
Min	135.25
Max	427
SD	140.05
Out of range	1
Missing/NA	422

Parameter Name	SupportWithdrawnTimeSinceInj
CRF Field	Time Since Injury (Support Withdrawn)
CRF Description	Time Since Injury (Support Withdrawn)
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Date & Time of Support Withdrawn– Date & Time of Injury
Permissible Range	> 0
Recommended Interpretation for missing/NA values	Expired, Not applicable/Not done, Unknown/Not reported
Comments	Hospital records available for 428 patients

Time Since Injury (Support Withdrawn)	Time (hours)
N	8
Mean	223.24
Median	193.25
Min	7
Max	427.5
SD	162.45
Out of range	0
Missing/NA	420

Parameter Name	HospDischTimeSinceInj
CRF Field	Time Since Injury (Hosp Discharge)
CRF Description	Time Since Injury (Hosp Discharge)
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Date & Time of Hospital Discharge– Date & Time of Injury
Permissible Range	> 0
Recommended Interpretation for missing/NA values	Expired, Unknown/Not reported
Comments	Hospital records available for 428 patients

Time Since Injury (Hosp Discharge)	Time (hours)
N	391
Mean	4691.84
Median	87.5
Min	13.75
Max	1753654
SD	88678
Out of range	1
Missing/NA	36

Parameter Name	DispHosp, *DispHospOther*
CRF Field	Discharge to
CRF Description	Disposition from Hospital
CRF Input Type	Dropdown, *Text area*
NIND 2.0 CDE ID	C04809
NIND 2.0 CDE Name	Hospital discharge destination type
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Expired, Unknown/Not reported
Comments	Hospital records available for 428 patients

Discharge to	Count (N)
1 – Other hospital	27
2 - Rehab unit	62
3 - Nursing home	3
4 - SNF	22
5 - Home	275
6 - Other	12
Missing/NA	26
Discharge to Other	*21*

Hospital	Hospital Admission/Discharge	Discharge Status

Parameter Name	DischargeStatus
CRF Field	Discharge Status
CRF Description	Status of patient @ time of discharge from hospital (dead or alive)
CRF Input Type	Radio button
NIND 2.0 CDE ID	C04807
NIND 2.0 CDE Name	Vital status
IMPACT 1.5 CDE	VITSTAT = vital status
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Hospital records available for 428 patients

Discharge Status	Count (N)
1 – Alive	395
0 - Dead	18
Missing/NA	15

Parameter Name	DeathTimeSinceInj
CRF Field	Time Since Injury (Death)
CRF Description	Time Since Injury (Death)
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Date & Time of Death– Date & Time of Injury
Permissible Range	> 0
Recommended Interpretation for missing/NA values	Expired, Unknown/Not reported
Comments	Hospital records available for 428 patients

Time Since Injury (Death)	Time (hours)
N	18
Mean	232.44
Median	162.26
Min	23.92
Max	722.77
SD	184.40
Out of range	0
Missing/NA	410

Parameter Name	DeathCause, *DeathCauseOther*
CRF Field	Principal Cause of Death
CRF Description	Cause of death
CRF Input Type	Dropdown, *Text area*
NIND 2.0 CDE ID	C04800
NIND 2.0 CDE Name	Death cause text
IMPACT 1.5 CDE	CAUSDEATH: Principal cause of death
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable, Unknown/Not reported
Comments	Hospital records available for 428 patients

Principal Cause of Death	Count (N)
1 – Head injury/initial injury	9
2 - Head injury/secondary intracranial damage	3
3 - Systemic trauma	0
4 - Medical complications	5
5 - Other	1
Missing/NA	410
Death Cause Other	*3*

Parameter Name	ComplYesNo
CRF Field	Does patient have complications?
CRF Description	
CRF Input Type	Radio button
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Expired, Unknown/Not reported
Comments	Hospital records available for 428 patients

Does patient have complications?	Count (N)
1 – Yes	153
0 - No	215
Missing/NA	60

Parameter Name	ComplRhinorrhea, ComplOtorrhea, ComplMeningitis, ComplSeizure, ComplVentriculitis, ComplStroke, ComplNeurogenicShock, ComplOtherCSFLeak, ComplOtherNeuro1, *ComplOtherNeuro1Txt*, ComplOtherNeuro2, C*omplOtherNeuro2Txt*
CRF Field	Rhinorrhea, Otorrhea, Meningitis, Seizure, Ventriculitis, Stroke, Neurogenic Shock, Other CSF Leak, Other, *ComplOtherNeuro1Txt*, Other, *ComplOtherNeuro2Txt*
CRF Description	Complications Neuro: Rhinorrhea, Otorrhea, Meningitis, Seizure, Ventriculitis, Stroke, Neurogenic Shock, Other CSF Leak, Other 1, *ComplOtherNeuro1Txt (Specify),* Other 2, *ComplOtherNeuro2Txt (Specify)*
CRF Input Type	Checkbox, *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Hospital records available for 428 patients

Complications Neurological	Yes (N)	No (N)	Missing/NA (N)
Rhinorrhea	2	422	4
Otorrhea	4	420	4
Meningitis	1	423	4
Seizure	17	407	4
Ventriculitis	0	424	4
Stroke	1	423	4
Neurogenic Shock	0	424	4
Other CSF Leak	1	423	4
Other	59	365	4
Complications Neuro: Other 1 (Specify)	*59*		*369*
Other	14	411	4
Complications Neuro: Other 2 (Specify)	*13*		*416*

Parameter Name	ComplCardiacArrest, ComplCHF, ComplDVT, ComplMajorArrhythmia, ComplMI, ComplHypertensionWTreatment, ComplHypotensionWTreatment, ComplHemorrhagicShock, CompOtherCardio1, *CompOtherCardio1Txt*, ComplOtherCardio2, *CompOtherCardio2Txt*
CRF Field	Cardiac Arrest, CHF, DVT, Major Arrhythmia, MI, Hypertension Requiring Treatment, Hypotension Requiring Treatment, Hemorrhagic Shock, Other, *CompOtherCardio1Txt*, Other, *CompOtherCardio2Txt*
CRF Description	Complications Cardio: Cardiac Arrest, CHF, DVT, Major Arrhythmia, MI, Hypertension Requiring Treatment, Hypotension Requiring Treatment, Hemorrhagic Shock, Other 1, *CompOtherCardio1Txt (Specify)*, Other 2, *CompOtherCardio2Txt (Specify)*
CRF Input Type	Checkbox, *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Hospital records available for 428 patients

Complications Cardiovascular	Yes (N)	No (N)	Missing/NA (N)
Cardiac Arrest	3	421	4
CHF	2	422	4
DVT	4	420	4
Major Arrhythmia	3	421	4
MI	0	424	4
Hypertension Requiring Treatment	38	386	4
Hypotension Requiring Treatment	35	389	4
Hemorrhagic Shock	1	423	4
Other	32	392	4
Complications Cardio: Other 1 (Specify)	*32*		*396*
Other	6	418	4
Complications Cardio: Other 2 (Specify)	*6*		*422*

Parameter Name	ComplCoagulopathy, ComplDIC, ComplAnemiaWTreatment, ComplOtherHematopoetic1, *ComplOtherHematopoetic1Txt*, ComplOtherHematopoetic2, *ComplOtherHematopoetic2Txt*
CRF Field	Coagulopathy, DIC, Anemia Requiring Treatment, Other, *ComplOtherHematopoetic1Txt*, Other, *ComplOtherHematopoetic2Txt*
CRF Description	Complications Hematopoetic: Coagulopathy, DIC, Anemia Requiring Treatment, Other 1, *ComplOtherHematopoetic1Tx (Specify)*, Other 2, *ComplOtherHematopoetic2Txt (Specify)*
CRF Input Type	Checkbox, *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Hospital records available for 428 patients

Complications Hematopoetic	Yes (N)	No (N)	Missing/NA (N)
Coagulopathy	8	420	4
DIC	1	423	4
Anemia Requiring Treatment	33	391	4
Other	13	411	4
Complications Hematopoetic: Other 1 (Specify)	*13*		*415*
Other	0	424	4
Complications Hematopoetic: Other 2 (Specify)	*0*		*428*

Parameter Name	ComplARDS, ComplFatEmbolus, ComplPE, ComplPleuralEffusion, ComplPneumonia, ComplPresumedPneumonia, ComplRespiratoryFailure, ComplVAP, ComplAsthma, ComplOtherPulmonary1, *CompOtherCardio1Txt*, ComplOtherPulmonary2, *CompOtherCardio2Txt*
CRF Field	ARDS, Fat Embolus, Pulmonary Embolism, Pleural Effusions, Pneumonia, Presumed Pneumonia, Respiratory Failure, VAP, Asthma, Other, *ComplOtherPulmonary1Txt*, Other, *ComplOtherPulmonary2Txt*
CRF Description	Complications Pulmonary: ARDS, Fat Embolus, Pulmonary Embolism, Pleural Effusions, Pneumonia, Presumed Pneumonia, Respiratory Failure, VAP, Asthma, Other 1, *ComplOtherPulmonary1Txt (Specify)*, Other 2, *ComplOtherPulmonary2Txt (Specify)*
CRF Input Type	Checkbox, *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Hospital records available for 428 patients

Complications Pulmonary	Yes (N)	No (N)	Missing/NA (N)
ARDS	4	420	4
Fat Embolus	0	424	4
Pulmonary Embolism	3	421	4
Pleural Effusions	4	420	4
Pneumonia	30	394	4
Presumed Pneumonia	17	407	4
Respiratory Failure	50	374	4
VAP	2	422	4
Asthma	0	424	4
Other	32	392	4
Complications Pulmonary: Other 1 (Specify)	*22*		*406*
Other	5	419	4
Complications Pulmonary: Other 2 (Specify)	*5*		*423*

Parameter Name	ComplAbdominalCompSyndr, ComplBowelObstruction, ComplGIBleed, ComplHepaticEncephalopathy, ComplHepaticFailure, ComplPancreatitis, ComplRenalFailure, ComplOtherGI1, *ComplOtherGI1Txt*, ComplOtherGI2, *ComplOtherGI2Txt*
CRF Field	Abdominal Compartment Syndrome, Bowel Obstruction, GI Bleed, Hepatic Encephalopathy, Hepatic Failure, Pancreatitis, Renal Failure, Other, *ComplOtherGI1Txt*, Other, *ComplOtherGI2Txt*
CRF Description	Complications GI/Abdomen: Abdominal Compartment Syndrome, Bowel Obstruction, GI Bleed, Hepatic Encephalopathy, Hepatic Failure, Pancreatitis, Renal Failure, Other 1, *ComplOtherGI1Txt (Specify)*, Other 2, *ComplOtherGI2Txt (Specify)*
CRF Input Type	Checkbox, *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Hospital records available for 428 patients

Complications GI/Abdomen	Yes (N)	No (N)	Missing/NA (N)
Abdominal Compartment Syndrome	0	424	4
Bowel Obstruction	1	423	4
GI Bleed	3	421	4
Hepatic Encephalopathy	0	424	4
Hepatic Failure	0	424	4
Pancreatitis	0	424	4
Renal Failure	3	421	4
Other	31	393	4
Complications Hematopoetic: Other 1 (Specify)	*31*		*397*
Other	3	421	4
Complications Hematopoetic: Other 2 (Specify)	*3*		*425*

Parameter Name	ComplAbcess, ComplSeromaHematoma, ComplWoundDehiscence, ComplWoundInfection, ComplPressureUlcer, ComplOtherWound1, *ComplOtherWound1Txt*, ComplOtherWound2, *ComplOtherWound2Txt*
CRF Field	Abcess, Seroma / hematoma / bleeding, Wound Dehiscence, Wound Infection, Pressure Ulcer, Other, *ComplOtherWound1Txt*, Other, *ComplOtherWound2Txt*
CRF Description	Complications Wound: Abcess, Seroma / hematoma / bleeding, Wound Dehiscence, Wound Infection, Pressure Ulcer, Other 1, *ComplOtherWound1Txt (Specify)*, Other 2, *ComplOtherWound2Txt (Specify)*
CRF Input Type	Checkbox, *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Hospital records available for 428 patients

Complications Wound	Yes (N)	No (N)	Missing/NA (N)
Abcess	0	424	4
Seroma / hematoma / bleeding	0	424	4
Wound Dehiscence	2	422	4
Wound Infection	2	422	4
Pressure Ulcer	0	424	4
Other	14	410	4
Complications Hematopoetic: Other 1 (Specify)	14		397
Other	3	421	4
Complications Hematopoetic: Other 2 (Specify)	3		425

Parameter Name	ComplHypoglycemia, ComplHyperglycemia, ComplHyponatremia, ComplHypernatremia, ComplPtPttInr, ComplOtherLabAbnorm1, *ComplOtherLabAbnorm1Txt*, ComplOtherLabAbnorm2, *ComplOtherLabAbnorm2Txt*
CRF Field	Hypoglycemia, Hyperglycemia, Hyponatremia, Hypernatremia, PT/PTT/INR Abnormality, Other, *ComplOtherLabAbnorm1Txt*, Other, *ComplOtherLabAbnorm2Txt*
CRF Description	Complications Lab Abnorm: Hypoglycemia, Hyperglycemia, Hyponatremia, Hypernatremia, PT/PTT/INR Abnormality, Other 1, *ComplOtherLabAbnorm1Txt (Specify)*, Other 2, *ComplOtherLabAbnorm2Txt (Specify)*
CRF Input Type	Checkbox, *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Hospital records available for 428 patients

Complications Lab Abnormalities	Yes (N)	No (N)	Missing/NA (N)
Hypoglycemia	1	423	4
Hyperglycemia	85	339	4
Hyponatremia	30	394	4
Hypernatremia	20	404	4
PT/PTT/INR Abnormality	44	380	4
Other	45	379	4
Complications Hematopoetic: Other 1 (Specify)	*45*		*383*
Other	20	404	4
Complications Hematopoetic: Other 2 (Specify)	*20*		*408*

Parameter Name	ComplBacteremia, ComplFever, ComplPresumedInfection, ComplSepsis, ComplSepticemia, ComplUTI, ComplSepticShock, ComplOtherInfection1, *ComplOtherInfection1Txt*, ComplOtherInfection2, *ComplOtherInfection2Txt*
CRF Field	Bacteremia, Fever (Temp>38.5) of unknown origin, Presumed Infection, Sepsis, Septicemia, UTI, Septic Shock, Other, *ComplOtherInfection1Txt*, Other, *ComplOtherInfection2Txt*
CRF Description	Complications Other Infections: Bacteremia, Fever (Temp>38.5) of unknown origin, Presumed Infection, Sepsis, Septicemia, UTI, Septic Shock, Other 1, *ComplOtherInfection1Txt (Specify)*, Other 2, *ComplOtherInfection2Txt (Specify)*
CRF Input Type	Checkbox, *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Hospital records available for 428 patients

Complications Infection Other Than Pneumonia/Wound	Yes (N)	No (N)	Missing/NA (N)
Bacteremia	4	420	4
Fever (Temp>38.5) of unknown origin	27	397	4
Presumed Infection	13	381	4
Sepsis	3	421	4
Septicemia	1	423	4
UTI	12	412	4
Septic Shock	1	423	4
Other	10	414	4
Complications Hematopoetic: Other 1 (Specify)	10		418
Other	3	421	4
Complications Hematopoetic: Other 2 (Specify)	3		425

Parameter Name	ComplMSOF, ComplTransfusionReaction
CRF Field	MSOF, Transfusion Reaction
CRF Description	Complications Other: MSOF, Transfusion Reaction
CRF Input Type	Checkbox
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Unknown/Not reported
Comments	Hospital records available for 428 patients

Complications Other Complications	Yes (N)	No (N)	Missing/NA (N)
MSOF	3	421	4
Transfusion Reaction	0	424	4

Parameter Name	SurgeryDescriptionICD9
CRF Field	ICD9Code
CRF Description	Inter-cranial Surgery code
CRF Input Type	Dropdown
NIND 2.0 CDE ID	C05108
NIND 2.0 CDE Name	Surgical or therapeutic procedure type
IMPACT 1.5 CDE	SurgTx_IC = Surgical Procedures Intracranial
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	Surgery records available for 137 patients

ICD9 Code	Count (N)
ICD9 Codes	321
Missing/NA	16

Parameter Name	SurgeryStartTimeSinceInj, SurgeryEndTimeSinceInj
CRF Field	Time Since Injury (Surgery Start), Time Since Injury (Surgery End)
CRF Description	Time Since Injury (Surgery Start), Time Since Injury (Surgery End)
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Date & Time of Surgery– Date & Time of Injury
Permissible Range	> 0
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	Surgery records available for 137 patients

Time Since Injury (Surgery)	Start (hours)	End (hours)
N	322	302
Mean	212.46	211.41
Median	39.45	36.75
Min	0.85	1.3
Max	8880.62	8882.2
SD	989.41	1018.8
Out of range	0	0
Missing/NA	29	49

Parameter Name	SurgeryTiming
CRF Field	Surgery Timing
CRF Description	Timing of surgery (Emergent, Elective, or Emergent return to OR)
CRF Input Type	Radio button
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	Surgery records available for 137 patients

Surgery Timing	Count (N)
1 - Emergent	178
2 - Elective	111
3 - Emergent return to OR	19
Missing/NA	43

Parameter Name	SurgeryHypotension, SurgeryHypoxia
CRF Field	Hypotension, Hypoxia
CRF Description	Was hypotension observed during surgery (check box), Was hypoxia observed during surgery (check box)
CRF Input Type	Radio button
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	Surgery records available for 137 patients

Hypotension/Hypoxia	Hypotension (N)	Hypoxia (N)
1 - Yes	51	15
0 - No	251	288
Missing/NA	49	48

Parameter Name	SurgerySBPLess90, SurgerySPO2Less95
CRF Field	# timesSBP< 90, # timesSpO2< 95
CRF Description	Number of times SBP was below 90, Number of times SPO2 was below 95
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	>= 0 (integer)
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	Surgery records available for 137 patients

Number of times	SBP< 90	SpO2< 95
N	235	228
0	181	210
1	10	9
2	17	0
3	6	1
4	12	0
5	0	1
6	3	0
7	2	1
8	0	3
12	1	0
Unknown/Non-numeric	3	3
Missing/NA	103	110

Parameter Name	ICPMonitorYesNo
CRF Field	ICP Monitor Used
CRF Description	
CRF Input Type	Radio button
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	ICPMonit = Intracranial Pressure Monitoring - Procedures
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	ICP Monitor records available for 335 patients

ICP Monitor Used	Count (N)
1 - Yes	46
0 - No	285
Missing/NA	37

Parameter Name	ICPUnit
CRF Field	Unit
CRF Description	Unit in which ICP Monitor was used
CRF Input Type	Radio button
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	ICP Monitor records available for 335 patients

Unit	Count (N)
1 - ED	4
2 - OR	8
3 - ICU	59
Missing/NA	297

Parameter Name	IICPLocation
CRF Field	ICPLocation
CRF Description	Location of ICP Monitor
CRF Input Type	Radio button
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	ICP Monitor records available for 335 patients

Location	Count (N)
1 - Right	25
2 - Left	14
Missing/NA	329

Parameter Name	ICPDevice, *ICPDeviceOther*
CRF Field	Device Used
CRF Description	Type of ICP Monitor
CRF Input Type	Dropdown, *Text area*
NIND 2.0 CDE ID	C01572
NIND 2.0 CDE Name	ICP device type
IMPACT 1.5 CDE	ICPMonit = Intracranial Pressure Monitoring - Procedures
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	ICP Monitor records available for 335 patients

Device Used	Count (N)
1 - Ventriculostomy	44
2 - Subdural	1
3 - Intraparenchymal	26
4 - Epidural	0
5 - Other	2
Missing/NA	295
Other ICP Device	*6*

Parameter Name	ICPInsTimeSinceInj, ICPRemTimeSinceInj
CRF Field	Time Since Injury (ICP Insert), Time Since Injury (ICP Removal)
CRF Description	Time Since Injury (ICP Insert), Time Since Injury (ICP Removal)
CRF Input Type	Text area
NIND 2.0 CDE ID	C01566, C01568
NIND 2.0 CDE Name	ICP monitoring start date and time, ICP monitoring stop date and time
IMPACT 1.5 CDE	ICPMonit = Intracranial Pressure Monitoring - Procedures
Variable Type	Numerical
Calculation Rule	Date & Time of ICP Mornitoring– Date & Time of Injury
Permissible Range	> 0
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	ICP Monitor records available for 335 patients

Time Since Injury (ICP Monitoring)	Insert (hours)	Removal (hours)
N	72	71
Mean	15.54	163.90
Median	9.23	132.5
Min	3.65	29.5
Max	153.5	487
SD	27.17	95.39
Out of range	0	0
Missing/NA	296	297

Parameter Name	ICPStopReason
CRF Field	Reason for Stopping
CRF Description	Reason for stopping using ICP Monitor
CRF Input Type	Dropdown
NIND 2.0 CDE ID	C01567
NIND 2.0 CDE Name	ICP monitoring stopped reason
IMPACT 1.5 CDE	ICPMonit = Intracranial Pressure Monitoring - Procedures
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done, Unknown/Not reported
Comments	ICP Monitor records available for 335 patients

Reason for Stopping	Count (N)
1 - Monitor/catheter failure	9
2 - Patient considered unsalvageable	3
3 - Patient died	8
4 - Clinically no longer required	51
Missing/NA	297

Parameter Name	BSI18Faintness
CRF Field	1. Faintness or dizziness
CRF Description	1. Faintness or dizziness
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

1. Faintness or dizziness	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		183
1- A little bit		95
2- Moderately		34
3- Quite a bit		23
4- Extremely		4
Missing/NA		260

Parameter Name	BSI18NoInterest
CRF Field	2. Feeling no interest in things
CRF Description	2. Feeling no interest in things
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

2. Feeling no interest in things	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		172
1- A little bit		80
2- Moderately		48
3- Quite a bit		29
4- Extremely		10
Missing/NA		260

Parameter Name	BSINervous
CRF Field	3. Nervousness or shakiness inside
CRF Description	3. Nervousness or shakiness inside
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

3. Nervousness or shakiness inside	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		181
1- A little bit		67
2- Moderately		59
3- Quite a bit		22
4- Extremely		10
Missing/NA		260

Parameter Name	BSI18ChestPain
CRF Field	4. Pains in heart or chest
CRF Description	4. Pains in heart or chest
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

4. Pains in heart or chest	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		259
1- A little bit		42
2- Moderately		24
3- Quite a bit		13
4- Extremely		1
Missing/NA		260

Parameter Name	BSI18FeelingLonely
CRF Field	5. Feeling lonely
CRF Description	5. Feeling lonely
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

5. Feeling lonely	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		187
1- A little bit		59
2- Moderately		49
3- Quite a bit		30
4- Extremely		14
Missing/NA		260

Parameter Name	BSI18FeelingTense
CRF Field	6. Feeling tense or keyed up
CRF Description	6. Feeling tense or keyed up
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

6. Feeling tense or keyed up	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		130
1- A little bit		83
2- Moderately		78
3- Quite a bit		40
4- Extremely		8
Missing/NA		260

Parameter Name	BSI18Nausea
CRF Field	7. Nausea or upset stomach
CRF Description	7. Nausea or upset stomach
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

7. Nausea or upset stomach	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		227
1- A little bit		45
2- Moderately		39
3- Quite a bit		17
4- Extremely		11
Missing/NA		260

Parameter Name	BSI18FeelingBlue
CRF Field	8. Feeling blue
CRF Description	8. Feeling blue
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

8. Feeling blue	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		158
1- A little bit		73
2- Moderately		69
3- Quite a bit		25
4- Extremely		14
Missing/NA		260

Parameter Name	BSI18Scared
CRF Field	9. Suddenly scared for no reason
CRF Description	9. Suddenly scared for no reason
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

9. Suddenly scared for no reason	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		250
1- A little bit		41
2- Moderately		23
3- Quite a bit		19
4- Extremely		5
Missing/NA		260

Parameter Name	BSI18TroubleGettingBreath
CRF Field	10. Trouble getting your breath
CRF Description	10. Trouble getting your breath
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

10. Trouble getting your breath	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		250
1- A little bit		51
2- Moderately		23
3- Quite a bit		6
4- Extremely		9
Missing/NA		260

Parameter Name	BSI18FeelingWorthless
CRF Field	11. Feelings of worthlessness
CRF Description	11. Feelings of worthlessness
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

11. Feelings of worthlessness	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		215
1- A little bit		63
2- Moderately		35
3- Quite a bit		15
4- Extremely		11
Missing/NA		260

Parameter Name	BSI18TerrorOrPanic
CRF Field	12. Spells or terror or panic
CRF Description	12. Spells or terror or panic
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

12. Spells or terror or panic	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		250
1- A little bit		45
2- Moderately		25
3- Quite a bit		10
4- Extremely		9
Missing/NA		260

Parameter Name	BSI18Numbness
CRF Field	13. Numbness or tingling in parts of your body
CRF Description	13. Numbness or tingling in parts of your body
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

13. Numbness or tingling in parts of your body	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		179
1- A little bit		67
2- Moderately		50
3- Quite a bit		29
4- Extremely		14
Missing/NA		260

Parameter Name	BSI18FeelingHopeless
CRF Field	14. Feeling hopeless about the future
CRF Description	14. Feeling hopeless about the future
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

14. Feeling hopeless about the future	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		190
1- A little bit		75
2- Moderately		41
3- Quite a bit		22
4- Extremely		11
Missing/NA		260

Parameter Name	BSI18FeelingRestless
CRF Field	15. Feeling so restless you couldn't sit still
CRF Description	15. Feeling so restless you couldn't sit still
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

15. Feeling so restless you couldn't sit still	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		192
1- A little bit		68
2- Moderately		35
3- Quite a bit		31
4- Extremely		13
Missing/NA		260

Parameter Name	BSI18FeelingWeak
CRF Field	16. Feeling weak in parts of your body
CRF Description	16. Feeling weak in parts of your body
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

16. Feeling weak in parts of your body	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		174
1- A little bit		57
2- Moderately		51
3- Quite a bit		36
4- Extremely		21
Missing/NA		260

Parameter Name	BSI18ThoughtsEndingLife
CRF Field	17. Thoughts of ending your life
CRF Description	17. Thoughts of ending your life
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

17. Thoughts of ending your life	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		302
1- A little bit		18
2- Moderately		8
3- Quite a bit		4
4- Extremely		7
Missing/NA		260

Parameter Name	BSI18FeelingFearful
CRF Field	18. Feeling fearful
CRF Description	18. Feeling fearful
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

18. Feeling fearful	Count at 3-month (N)	Count at 6-month (N)
0- Not at all		229
1- A little bit		62
2- Moderately		33
3- Quite a bit		10
4- Extremely		5
Missing/NA		260

Outcomes → Brief Symptom Inventory (2) → BSI18 Raw Score

Parameter Name	BSI18SomScoreRaw, BSI18DeprScoreRaw, BSI18AnxScoreRaw, BSI18GSIScoreRaw
CRF Field	Raw Score Somatization, Raw Score Depression, Raw Score Anxiety, Raw Score GSI
CRF Description	Raw Score Somatization, Raw Score Depression, Raw Score Anxiety, Raw Score GSI
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	sum of q1+4+7+10+13+16, sum of q2+5+8+11+14+17, sum of q3+6+9+12+15+18, sum of all questions
Permissible Range	0-24, 0-24, 0-24, 0-72
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

Raw Score at 6-month	Somatization	Depression	Anxiety	GSI
N	339	339	339	339
Mean	4.16	4.46	4.33	12.95
Median	3	2	3	9
Min	0	0	0	0
Max	23	24	24	61
SD	4.53	5.08	4.85	12.81
Out of range (0 but individual scores are null)	1	1	1	0
Missing/NA	260	260	260	260

Parameter Name	BSI18SomScoreT, BSI18DeprScoreT, BSI18AnxScoreT, BSI18GSIScoreT
CRF Field	T Score Somatization, T Score Depression, T Score Anxiety, T Score GSI
CRF Description	T Score Somatization, T Score Depression, T Score Anxiety, T Score GSI
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	T scores based on raw scores and gender
Permissible Range	30-81
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 339 patients

T Score at 6-month	Somatization	Depression	Anxiety	GSI
N	339	339	339	339
Mean	54.95	53.24	52.74	54.67
Median	56	48	50	64
Min	41	40	38	33
Max	81	81	81	81
SD	10.73	11.23	11.45	11.41
Out of range	0	0	0	0
Missing/NA	260	260	260	260

Parameter Name	PCLImages
CRF Field	1. Repeated, disturbing memories, thoughts, or images of a stressful experience from the past?
CRF Description	1. Repeated, disturbing memories, thoughts, or images of a stressful experience from the past?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

1. Repeated, disturbing memories, thoughts, or images of a stressful experience from the past?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		160
2- A little bit		84
3- Moderately		37
4- Quite a bit		43
5- Extremely		14
Missing/NA		261

Parameter Name	PCLDreams
CRF Field	2. Repeated, disturbing dreams of a stressful experience from the past?
CRF Description	2. Repeated, disturbing dreams of a stressful experience from the past?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

2. Repeated, disturbing dreams of a stressful experience from the past?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		221
2- A little bit		54
3- Moderately		33
4- Quite a bit		21
5- Extremely		9
Missing/NA		261

Parameter Name	PCLFeeling
CRF Field	3. Suddenly acting or feeling as if a stressful experience were happening again (as if you were reliving it)?
CRF Description	3. Suddenly acting or feeling as if a stressful experience were happening again (as if you were reliving it)?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

3. Suddenly acting or feeling as if a stressful experience were happening again?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		214
2- A little bit		55
3- Moderately		40
4- Quite a bit		24
5- Extremely		5
Missing/NA		261

Parameter Name	PCLVeryUpset
CRF Field	4. Feeling very upset when something reminded you of a stressful experience from the past?
CRF Description	4. Feeling very upset when something reminded you of a stressful experience from the past?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

4. Feeling very upset when something reminded you of a stressful experience from the past?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		154
2- A little bit		73
3- Moderately		59
4- Quite a bit		32
5- Extremely		20
Missing/NA		261

Parameter Name	PCLPhysicalReactions
CRF Field	5. Having physical reactions (e.g., heart pounding, trouble breathing, or sweating) when something reminded you of a stressful experience from the past?
CRF Description	5. Having physical reactions (e.g., heart pounding, trouble breathing, or sweating) when something reminded you of a stressful experience from the past?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

5. Having physical reactions when something reminded you of a stressful experience from the past?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		217
2- A little bit		53
3- Moderately		31
4- Quite a bit		20
5- Extremely		17
Missing/NA		261

Parameter Name	PCLThinking
CRF Field	6. Avoid thinking about or talking about a stressful experience from the past or avoid having feelings related to it?
CRF Description	6. Avoid thinking about or talking about a stressful experience from the past or avoid having feelings related to it?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

6. Avoid thinking about or talking about a stressful experience from the past or avoid having feelings related to it?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		182
2- A little bit		53
3- Moderately		54
4- Quite a bit		30
5- Extremely		19
Missing/NA		261

Parameter Name	PCLActivities
CRF Field	7. Avoid activities or situations because they remind you of a stressful experience from the past?
CRF Description	7. Avoid activities or situations because they remind you of a stressful experience from the past?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

7. Avoid activities or situations because they remind you of a stressful experience from the past?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		180
2- A little bit		63
3- Moderately		43
4- Quite a bit		28
5- Extremely		24
Missing/NA		261

Parameter Name	PCLRemembering
CRF Field	8. Trouble remembering important parts of a stressful experience from the past?
CRF Description	8. Trouble remembering important parts of a stressful experience from the past?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

8. Trouble remembering important parts of a stressful experience from the past?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		162
2- A little bit		61
3- Moderately		33
4- Quite a bit		34
5- Extremely		47
Missing/NA		261

Parameter Name	PCLLossOfInterest
CRF Field	9. Loss of interest in things that you used to enjoy?
CRF Description	9. Loss of interest in things that you used to enjoy?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

9. Loss of interest in things that you used to enjoy?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		189
2- A little bit		54
3- Moderately		45
4- Quite a bit		34
5- Extremely		16
Missing/NA		261

Parameter Name	PCLDistant
CRF Field	10. Feeling distant or cut off from other people?
CRF Description	10. Feeling distant or cut off from other people?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

10. Feeling distant or cut off from other people?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		173
2- A little bit		64
3- Moderately		44
4- Quite a bit		41
5- Extremely		16
Missing/NA		261

Parameter Name	PCLEmotionallyNumb
CRF Field	11.Feeling emotionally numb or being unable to have loving feelings for those close to you?
CRF Description	11.Feeling emotionally numb or being unable to have loving feelings for those close to you?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

11.Feeling emotionally numb or being unable to have loving feelings for those close to you?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		221
2- A little bit		56
3- Moderately		34
4- Quite a bit		18
5- Extremely		9
Missing/NA		261

Parameter Name	PCLFuture
CRF Field	12. Feeling as if your future will somehow be cut short?
CRF Description	12. Feeling as if your future will somehow be cut short?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

12. Feeling as if your future will somehow be cut short?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		204
2- A little bit		64
3- Moderately		27
4- Quite a bit		31
5- Extremely		12
Missing/NA		261

Parameter Name	PCLAsleep
CRF Field	13. Trouble falling or staying asleep?
CRF Description	13. Trouble falling or staying asleep?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

13. Trouble falling or staying asleep?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		159
2- A little bit		54
3- Moderately		36
4- Quite a bit		42
5- Extremely		47
Missing/NA		261

Parameter Name	PCLIrritable
CRF Field	14. Feeling irritable or having angry outbursts?
CRF Description	14. Feeling irritable or having angry outbursts?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

14. Feeling irritable or having angry outbursts?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		157
2- A little bit		91
3- Moderately		52
4- Quite a bit		22
5- Extremely		16
Missing/NA		261

Parameter Name	PCLConcentrating
CRF Field	15. Having difficulty concentrating?
CRF Description	15. Having difficulty concentrating?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

15. Having difficulty concentrating?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		143
2- A little bit		79
3- Moderately		58
4- Quite a bit		34
5- Extremely		24
Missing/NA		261

Parameter Name	PCLSuperAlert
CRF Field	16. Being super alert or watchful on guard?
CRF Description	16. Being super alert or watchful on guard?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

16. Being super alert or watchful on guard?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		167
2- A little bit		59
3- Moderately		49
4- Quite a bit		37
5- Extremely		26
Missing/NA		261

Parameter Name	PCLJumpy
CRF Field	17. Feeling jumpy or easily startled?
CRF Description	17. Feeling jumpy or easily startled?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

17. Feeling jumpy or easily startled?	Count at 3-month (N)	Count at 6-month (N)
1- Not at all		197
2- A little bit		63
3- Moderately		40
4- Quite a bit		19
5- Extremely		19
Missing/NA		261

Parameter Name	PCLTotalScore
CRF Field	Total Score
CRF Description	Total Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Sum of question 1-17
Permissible Range	17-85
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

Total Score	3-month	6-month
N		338
Mean		32.98
Median		28
Min		17
Max		83
SD		14.80
Out of range		0
Missing/NA		261

Parameter Name	PCLIndexInjuryOrNot
CRF Field	18. Was the stressful experience the index head trauma that caused you to be seen at the study hospital or was it a different experience?
CRF Description	18. Was the stressful experience the index head trauma that caused you to be seen at the study hospital or was it a different experience?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

18. Was the stressful experience from head trauma or was it a different experience?	Count at 3-month (N)	Count at 6-month (N)
1 - Head Trauma		147
2 - Different Exp		53
3 -Both		52
Missing/NA		347

Parameter Name	PCLHowLongDidOtherExperienceOccur, PCLDifferentExperienceTimeRange
CRF Field	19. If different experience from question 18, how long ago did the stressful experience occur?
CRF Description	19. If different experience from question 18, how long ago did the stressful experience occur?
CRF Input Type	Text area, Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical, Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 338 patients

19. If different experience from question 18, how long ago did the stressful experience occur?	Count at 3-month (N)	Count at 6-month (N)
N (numerical)		84
1 - weeks		2
2 - months		17
3 - years		78
Missing/NA		502

Parameter Name	CVLTTrial1RawScore, CVLTTrial1StandardScore
CRF Field	Trial 1 Free Recall Correct Raw Score, Trial 1 Free Recall Correct Standard Score
CRF Description	Trial 1 Free Recall Correct Raw Score, Trial 1 Free Recall Correct Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Standard score from raw score and age range/gender
Permissible Range	0-16, -5.0-5.0
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

Trial 1 Free Recall Correct at 6-month	Raw Score	Standard Score
N	296	296
Mean	6.34	-0.26
Median	6	-0.5
Min	1	-3
Max	13	4
SD	2.29	1.25
Out of range	0	0
Missing/NA	303	303

Parameter Name	CVLTTrial2RawScore, CVLTTrial2StandardScore
CRF Field	Trial 2 Free Recall Correct Raw Score, Trial 2 Free Recall Correct Standard Score
CRF Description	Trial 2 Free Recall Correct Raw Score, Trial 2 Free Recall Correct Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Standard score from raw score and age range/gender
Permissible Range	0-16, -5.0-5.0
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

Trial 2 Free Recall Correct at 6-month	Raw Score	Standard Score
N	293	293
Mean	8.98	-0.14
Median	9	-0.5
Min	1	-3.5
Max	16	3
SD	2.82	1.13
Out of range	0	0
Missing/NA	306	306

Parameter Name	CVLTTrial3RawScore, CVLTTrial3StandardScore
CRF Field	Trial 3 Free Recall Correct Raw Score, Trial 3 Free Recall Correct Standard Score
CRF Description	Trial 3 Free Recall Correct Raw Score, Trial 3 Free Recall Correct Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Standard score from raw score and age range/gender
Permissible Range	0-16, -5.0-5.0
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

Trial 3 Free Recall Correct at 6-month	Raw Score	Standard Score
N	293	293
Mean	10.41	-0.13
Median	10	0
Min	3	-2.5
Max	16	2
SD	2.90	1.08
Out of range	0	0
Missing/NA	306	306

Parameter Name	CVLTTrial4RawScore, CVLTTrial4StandardScore
CRF Field	Trial 4 Free Recall Correct Raw Score, Trial 4 Free Recall Correct Standard Score
CRF Description	Trial 4 Free Recall Correct Raw Score, Trial 4 Free Recall Correct Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Standard score from raw score and age range/gender
Permissible Range	0-16, -5.0-5.0
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

Trial 4 Free Recall Correct at 6-month	Raw Score	Standard Score
N	293	293
Mean	11.03	-0.20
Median	11	0
Min	1	-3.5
Max	16	2.5
SD	3.02	1.17
Out of range	0	0
Missing/NA	306	306

Parameter Name	CVLTTrial5RawScore, CVLTTrial5StandardScore
CRF Field	Trial 5 Free Recall Correct Raw Score, Trial 5 Free Recall Correct Standard Score
CRF Description	Trial 5 Free Recall Correct Raw Score, Trial 5 Free Recall Correct Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Standard score from raw score and age range/gender
Permissible Range	0-16, -5.0-5.0
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

Trial 5 Free Recall Correct at 6-month	Raw Score	Standard Score
N	296	296
Mean	11.78	-0.20
Median	12	0
Min	0	-4.5
Max	16	2
SD	3.01	1.18
Out of range	0	0
Missing/NA	303	303

Parameter Name	CVLTTrial1To5RawScore, CVLTTrial1To5StandardScore
CRF Field	Trials 1-5 Free Recall Total Correct Raw Score, Trials 1-5 Free Recall Total Correct Standard Score
CRF Description	Trials 1-5 Free Recall Total Correct Raw Score, Trials 1-5 Free Recall Total Correct Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Sum of trial 1-5 correct, Standard score from raw score and age range/gender
Permissible Range	0-80, 5-95
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

Trial 1-5 Free Recall Total Correct at 6-month	Raw Score	Standard Score
N	296	296
Mean	48.48	50.61
Median	49	50
Min	13	18
Max	77	83
SD	12.40	12.25
Out of range	0	0
Missing/NA	303	303

Parameter Name	CVLTTrialBRawScore, CVLTTrialBStandardScore
CRF Field	List B Free Recall Correct Raw Score, List B Free Recall Correct Standard Score
CRF Description	List B Free Recall Correct Raw Score, List B Free Recall Correct Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Standard score from raw score and age range/gender
Permissible Range	0-16, -5.0-5.0
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

List B Free Recall Correct at 6-month	Raw Score	Standard Score
N	296	296
Mean	5.60	-0.33
Median	5	-0.5
Min	0	-3.5
Max	14	3.5
SD	2.36	1.17
Out of range	0	0
Missing/NA	303	303

Parameter Name	CVLTShortDelayFreeRecallRawScore, CVLTShortDelayFreeRecallStandardScore
CRF Field	Short Delay Free Recall Correct Raw Score, Short Delay Free Recall Correct Standard Score
CRF Description	Short Delay Free Recall Correct Raw Score, Short Delay Free Recall Correct Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Standard score from raw score and age range/gender
Permissible Range	0-16, -5.0-5.0
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

Short Delay Free Recall Correct at 6-month	Raw Score	Standard Score
N	296	296
Mean	10.09	-0.03
Median	10	0
Min	0	-3.5
Max	16	2
SD	3.66	1.15
Out of range	0	0
Missing/NA	303	303

Parameter Name	CVLTShortDelayCuedRecallRawScore, CVLTShortDelayCuedRecallStandardScore
CRF Field	Short Delay Cued Recall Correct Raw Score, Short Delay Cued Recall Correct Standard Score
CRF Description	Short Delay Cued Recall Correct Raw Score, Short Delay Cued Recall Correct Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Standard score from raw score and age range/gender
Permissible Range	0-16, -5.0-5.0
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

Short Delay Cued Recall Correct at 6-month	Raw Score	Standard Score
N	296	296
Mean	11.31	-0.08
Median	12	0
Min	0	-4
Max	16	2.5
SD	3.24	1.13
Out of range	0	0
Missing/NA	303	303

Parameter Name	CVLTLongDelayFreeRecallRawScore, CVLTLongDelayFreeRecallStandardScore
CRF Field	Long Delay Free Recall Correct Raw Score, Long Delay Free Recall Correct Standard Score
CRF Description	Long Delay Free Recall Correct Raw Score, Long Delay Free Recall Correct Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Standard score from raw score and age range/gender
Permissible Range	0-16, -5.0-5.0
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

Long Delay Free Recall Correct at 6-month	Raw Score	Standard Score
N	295	295
Mean	10.65	-0.07
Median	11	0
Min	0	-3
Max	16	2.5
SD	3.69	1.16
Out of range	0	0
Missing/NA	304	304

Parameter Name	CVLTLongDelayCuedRecallRawScore, CVLTLongDelayCuedRecallStandardScore
CRF Field	Long Delay Cued Recall Correct Raw Score, Long Delay Cued Recall Correct Standard Score
CRF Description	Long Delay Cued Recall Correct Raw Score, Long Delay Cued Recall Correct Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Standard score from raw score and age range/gender
Permissible Range	0-16, -5.0-5.0
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

Long Delay Cued Recall Correct at 6-month	Raw Score	Standard Score
N	295	295
Mean	11.27	-0.20
Median	12	0
Min	0	-3.5
Max	16	2
SD	3.50	1.16
Out of range	0	0
Missing/NA	304	304

Parameter Name	CVLTFreeRecallIntrusionsRaw, CVLTFreeRecallIntrusionsStandard
CRF Field	Free-Recall Intrusions Raw Score, Free-Recall Intrusions Standard Score
CRF Description	Free-Recall Intrusions Raw Score, Free-Recall Intrusions Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Standard score from raw score and age range/gender
Permissible Range	0-≥20, -5.0-5.0
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

Free Recall Intrusions at 6-month	Raw Score	Standard Score
N	293	293
Mean	2.03	0.06
Median	1	0
Min	0	-1
Max	20	5
SD	2.89	0.98
Out of range	0	0
Missing/NA	306	306

Parameter Name	CVLTCuedRecallIntrusionsRaw, CVLTCuedRecallIntrusionsStandard
CRF Field	Cued-Recall Intrusions Raw Score, Cued-Recall Intrusions Standard Score
CRF Description	Cued-Recall Intrusions Raw Score, Cued-Recall Intrusions Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Standard score from raw score and age range/gender
Permissible Range	0-≥27, -5.0-5.0
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

Cued Recall Intrusions at 6-month	Raw Score	Standard Score
N	293	293
Mean	1.59	0.03
Median	1	-0.5
Min	0	-1
Max	14	5
SD	2.25	0.87
Out of range	0	0
Missing/NA	306	306

Parameter Name	CVLTTotalIntrusionsRaw, CVLTTotalIntrusionsStandard
CRF Field	Total Intrusions Raw Score, Total Intrusions Standard Score
CRF Description	Total Intrusions Raw Score, Total Intrusions Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Standard score from raw score and age range/gender
Permissible Range	0-≥37, -5.0-5.0
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

Total Intrusions at 6-month	Raw Score	Standard Score
N	293	293
Mean	3.62	0.03
Median	2	0
Min	0	-1.5
Max	29	5
SD	4.65	1.06
Out of range	0	0
Missing/NA	306	306

Outcomes	CVLT	Total Repetitions

Parameter Name	CVLTTotalRepetitionsRaw, CVLTTotalRepetitionsStandard
CRF Field	Total Repetitions Raw Score, Total Repetitions Standard Score
CRF Description	Total Repetitions Raw Score, Total Repetitions Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Standard score from raw score and age range/gender
Permissible Range	0-≥33, -5.0-5.0
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

Total Repetitions at 6-month	Raw Score	Standard Score
N	293	293
Mean	5.25	0.22
Median	4	0
Min	0	-1.5
Max	27	5
SD	5.04	1.16
Out of range	0	0
Missing/NA	306	306

Parameter Name	CVLTTotalRecognitionHitsRawScore, CVLTTotalRecognitionHitsStandardScore
CRF Field	Long-Delay Yes/No Recognition Hits Raw Score, Long-Delay Yes/No Recognition Hits Standard Score
CRF Description	Long-Delay Yes/No Recognition Hits Raw Score, Long-Delay Yes/No Recognition Hits Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Standard score from raw score and age range/gender
Permissible Range	0-16, -5.0-5.0
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

Long-Delay Yes/No Recognition Hits at 6-month	Raw Score	Standard Score
N	295	295
Mean	14.62	-0.21
Median	15	0
Min	0	-5
Max	16	1
SD	2.07	1.09
Out of range	0	0
Missing/NA	304	304

Parameter Name	CVLTTotalRecognitionDiscriminabilityRawScore, CVLTTotalRecognitionDiscriminabilityStandardScore
CRF Field	Total Recognition Discriminability Raw Score, Total Recognition Discriminability Standard Score
CRF Description	Total Recognition Discriminability Raw Score, Total Recognition Discriminability Standard Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Standard score from raw score and age range/gender
Permissible Range	-4.0-4.0, -5.0-5.0
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 296 patients

Total Recognition Discriminability at 6-month	Raw Score	Standard Score
N	295	295
Mean	3.01	0.05
Median	3.1	0
Min	0.3	-3.5
Max	4	2
SD	0.87	1.04
Out of range	0	0
Missing/NA	304	304

Parameter Name	CHARTSFAssistPaidHours, CHARTSFAssistUnpaidHours
CRF Field	
CRF Description	1. How many hours in a typical 24-hour day do you have someone with you to provide physical assistance for personal care activities such as eating, bathing, dressing, toileting and mobility? Hours Paid Assistance, Hours unpaid (family, others)
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 1 at 6-month	Hours Paid Assistance	Hours unpaid
N	332	332
Mean	0.27	0.74
Median	0	0
Min	0	0
Max	24	24
SD	2.33	3.86
Out of range	0	0
Missing/NA	268	267

Parameter Name	CHARTSFInHomeAssistTime
CRF Field	
CRF Description	2. How much time is someone with you in your home to assist you with activities that require remembering, decision making, or judgment?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 2 at 6-month	Count (N)
1- Someone else is always with me to observe or supervise	11
2- Someone else is always around, but they only check on me now and then	6
3- Sometimes I am left alone for an hour or two	5
4- Sometimes I am left alone for most of the day	4
5- I have been left alone all day and all night, but someone checks in on me	7
6 - I am left alone without anyone checking on me	299
Missing/NA	267

Parameter Name	CHARTSFOutHomeAssistTime
CRF Field	
CRF Description	3. How much of the time is someone with you to help you with remembering, decision making, or judgment when you go away from your home?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 3 at 6-month	Count (N)
1- I am restricted from leaving, even with someone else	3
2- Someone is always with me to help with remembering, decision making, or judgment when I go anywhere	27
3- I go to places on my own as long as they are familiar	8
4- I do not need help going anywhere	294
Missing/NA	227

Parameter Name	CHARTSFOutOfBedHours
CRF Field	
CRF Description	4. On a typical day, how many hours are you out of bed?
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 4 at 6-month	Hours
N	332
Mean	15.36
Median	16
Min	0
Max	21
SD	3.16
Out of range	0
Missing/NA	267

Parameter Name	CHARTSFOutOfHouseDays
CRF Field	
CRF Description	5. In a typical week, how many days do you get out of your house and go somewhere?
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 5 at 6-month	Days
N	332
Mean	5.82
Median	7
Min	0
Max	7
SD	1.77
Out of range	0
Missing/NA	267

Parameter Name	CHARTSFAwayFromHomeNights
CRF Field	
CRF Description	6. In the last year, how many nights have you spent away from your home (excluding hospitalizations?)
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 6 at 6-month	Count (N)
0 - None	61
1 -1-2	23
3 – 3-4	20
5 – 5 or more	228
Missing/NA	267

Parameter Name	CHARTSFPaidJobHours, *CHARTSFOccupation*
CRF Field	
CRF Description	7. How many hours per week do you spend working in a job for which you get paid?, *Occupation:*
CRF Input Type	Text area, *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical , Text
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 7 at 6-month	Hours
N	332
Mean	17.69
Median	0
Min	0
Max	100
SD	22.41
Out of range (non-numeric)	1
Missing/NA	266
Occupation (N)	*200*

Parameter Name	CHARTSFStudyHours
CRF Field	
CRF Description	8. How many hours per week do you spend in school working toward a degree or in an accredited technical training program (including hours in class and studying)?
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 8 at 6-month	Hours
N	332
Mean	3.36
Median	0
Min	0
Max	60
SD	10.36
Out of range (non-numeric)	0
Missing/NA	267

Parameter Name	CHARTSFHomemakingHours
CRF Field	
CRF Description	9. How many hours per week do you spend in active homemaking including parenting, housekeeping, and food preparation?
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 9 at 6-month	Hours
N	332
Mean	13.18
Median	8
Min	0
Max	84
SD	14.00
Out of range (non-numeric)	0
Missing/NA	267

Parameter Name	CHARTSFMaintenanceHours
CRF Field	
CRF Description	10. How many hours per week do you spend in home maintenance activities such as gardening, house repairs or home improvement?
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 10 at 6-month	Hours
N	332
Mean	3.59
Median	1
Min	0
Max	70
SD	7.66
Out of range (non-numeric)	0
Missing/NA	267

Parameter Name	CHARTSFRecreationHours
CRF Field	
CRF Description	11. How many hours per week do you spend in recreational activities such as sports, exercise, playing cards, or going to movies?
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 11 at 6-month	Hours
N	331
Mean	13.27
Median	10
Min	0
Max	90
SD	13.01
Out of range (non-numeric)	0
Missing/NA	268

Parameter Name	CHARTSFLiveWith
CRF Field	
CRF Description	12. How many other people do you live with?
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 12 at 6-month	Number of people
N	332
Mean	2.56
Median	1
Min	0
Max	92
SD	7.22
Out of range (non-numeric)	0
Missing/NA	267

Parameter Name	CHARTSFSpouse
CRF Field	
CRF Description	13. Is one of them your spouse or significant other?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 13 at 6-month	Count (N)
0 - No	141
1 - Yes	134
9 – N/A (lives alone)	51
Missing/NA	273

Parameter Name	CHARTSFRelatives
CRF Field	
CRF Description	14. Of the people you live with, how many are relatives (not including your spouse)?
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 14 at 6-month	Number of people
N	332
Mean	0.83
Median	0
Min	0
Max	7
SD	1.40
Out of range (non-numeric)	1
Missing/NA	266

Parameter Name	CHARTSFRelatives
CRF Field	
CRF Description	15. How many business or organizational associates do you visit, phone, or write to at least once a month?
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 15 at 6-month	Number of people
N	332
Mean	15.38
Median	3
Min	0
Max	500
SD	45.22
Out of range (non-numeric)	1
Missing/NA	266

Parameter Name	CHARTSFContactFriends
CRF Field	
CRF Description	16. How many friends (non-relatives contacted outside business or organizational settings) do you visit, phone, or write to at least once a month?
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 16 at 6-month	Number of people
N	332
Mean	15.24
Median	7
Min	0
Max	300
SD	31.74
Out of range (non-numeric)	0
Missing/NA	267

Parameter Name	CHARTSFContactStrangers
CRF Field	
CRF Description	17. With how many strangers have you initiated a conversation in the last month (for example, to ask information or place an order)?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 17 at 6-month	Count (N)
0 - No	25
1 – 1-2	41
3 – 3-5	57
6 – 6 or more	209
Missing/NA	267

Parameter Name	CHARTSFIncome
CRF Field	
CRF Description	18. Approximately what was the combined annual income, in the last year, of all family members in your household?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 18 at 6-month	Count (N)
5000 - Less than 10,000	33
12500 - Less than 15,000	20
17500 - Less than 20,000	15
22500 - Less than 25,000	51
30000 - Less than 35,000	42
42500 - Less than 50,000	38
62500 - Less than 75,000	38
80000 - 75,000 or more	74
Missing/NA	288

Parameter Name	CHARTSFMedicalCareExpenses
CRF Field	
CRF Description	19. Approximately how much did you pay last year for medical care expenses?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Question 19 at 6-month	Count (N)
500 - Less than 1000	155
1750 - Less than 2500	61
3750 - Less than 5000	33
7500 - Less than 10000	25
15000 - 10000 or more	34
Missing/NA	291

Parameter Name	CHARTSFPhysicalTotal, CHARTSFCognitiveTotal, CHARTSFMobilityTotal, CHARTSFOccupationTotal, CHARTSFSocialIntegrationTotal, CHARTSFSelfSufficientTotal
CRF Field	
CRF Description	Physical Total, Cognitive Total, Mobility Total, Occupation Total, Social Integration Total, Self Sufficient Total
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 332 patients

CHART-SF Scoring at 6-month	Physical Total	Cognitive Total	Mobility Total	Occupation Total	Social Integration Total	Self Sufficient Total
N	332	332	332	332	332	305
Mean	95.93	93.18	92.69	75.49	91.66	77.21
Median	100	100	100	100	100	100
Min	4	0	0	0	0	0
Max	100	100	100	100	100	100
SD	17.88	20.21	14.85	32.75	18.68	32.76
Out of range	0	0	0	0	0	0
Missing/NA	267	267	267	267	267	294

Parameter Name	GOSEResponse
CRF Field	Respondent:
CRF Description	Person responding to GOSE
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Person responding to GOSE	Count at 3-month (N)	Count at 6-month (N)
0 - Patient alone	389	353
1 - Relative/friend/caretaker alone	27	22
2 - Patient plus relative/friend/caretaker	11	7
Missing/NA	172	217

Parameter Name	GOSESimpleCommands
CRF Field	1. Is the head-injured person able to obey simple commands or say any words?
CRF Description	1. Is the head-injured person able to obey simple commands or say any words?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

GOSE Question 1	Count at 3-month (N)	Count at 6-month (N)
0 – No (VS)	2	1
1 - Yes	428	381
Missing/NA	169	217

Parameter Name	GOSEAssistanceNeeded, GOSENeedFreqHelp, GOSEIndependentBefore
CRF Field	2a. Is the assistance of another person at home essential every day for some activities of daily living?, 2b. Do they need frequent help of someone to be around at home most of the time?, 2c. Was assistance at home essential before the injury?
CRF Description	2a. Is the assistance of another person at home essential every day for some activities of daily living?, 2b. Do they need frequent help of someone to be around at home most of the time?, 2c. Was assistance at home essential before the injury?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

GOSE Question 2	Count at 3-month (N)	Count at 6-month (N)
2a. Assistance needed		
0 – No	379	351
1 - Yes	51	29
Missing/NA	169	219
2b. Need frequent help		
0 – No (upper SD)	20	11
1 - Yes (lower SD)	32	18
Missing/NA	547	570
2c. Independent before		
0 – No	43	25
1 - Yes	8	3
Missing/NA	548	571

Parameter Name	GOSEShopAlone, GOSEShopAloneBefore
CRF Field	3a. Are they able to shop without assistance?, 3b. Were they able to shop without assistance before?
CRF Description	3a. Are they able to shop without assistance?, 3b. Were they able to shop without assistance before?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

GOSE Question 3	Count at 3-month (N)	Count at 6-month (N)
3a. Able to shop alone		
0 – No (upper SD)	46	24
1 - Yes	379	353
Missing/NA	174	222
3b. Shop alone before		
0 – No	12	4
1 - Yes	376	347
Missing/NA	211	248

Parameter Name	GOSETravelAlone, GOSETravelAloneBefore
CRF Field	4a. Are they able to travel locally without assistance?, 4b. Were they able to travel locally without assistance before the injury?
CRF Description	4a. Are they able to travel locally without assistance?, 4b. Were they able to travel locally without assistance before the injury?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

GOSE Question 4	Count at 3-month (N)	Count at 6-month (N)
4a. Able to travel alone		
0 – No (upper SD)	47	27
1 - Yes	381	350
Missing/NA	171	222
4b. Travel alone before		
0 – No	13	5
1 - Yes	375	349
Missing/NA	211	245

Parameter Name	GOSEWork, GOSEWorkRestriction, GOSEWorkRestrictChange
CRF Field	5a. Are they currently able to work (or look after others at home) to their previous capacity?, 5b. How restricted are they?, 5c. Were they either working or seeking employment before the injury (answer 'yes') or were they doing neither (answer 'no')?
CRF Description	5a. Are they currently able to work (or look after others at home) to their previous capacity?, 5b. How restricted are they?, 5c. Were they either working or seeking employment before the injury (answer 'yes') or were they doing neither (answer 'no')?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

GOSE Question 5	Count at 3-month (N)	Count at 6-month (N)
5a. Able to work		
0 – No	154	115
1 - Yes	276	261
Missing/NA	169	223
5b. Work restriction		
1 - Reduced work capacity (upper MD)	82	55
2 - Able to work only in a sheltered workshop or non-competitive job or currently unable to work (Lower MD)	68	52
Missing/NA	449	492
5c. Work restriction change		
0 – No	47	34
1 - Yes	102	82
Missing/NA	450	483

Parameter Name	GOSEResumeSocialActivity, GOSESocialActivityRestrict, GOSESocialActivityRestrictChange
CRF Field	6a. Are they able to resume regular social and leisure activities outside home?, 6b. What is the extent of restriction on their social and leisure activities?, 6c. Did they engage in regular social and leisure activities outside home before the injury?
CRF Description	6a. Are they able to resume regular social and leisure activities outside home?, 6b. What is the extent of restriction on their social and leisure activities?, 6c. Did they engage in regular social and leisure activities outside home before the injury?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

GOSE Question 6	Count at 3-month (N)	Count at 6-month (N)
6a. Able to resume social activity		
0 – No	168	118
1 – Yes	260	260
Missing/NA	171	221
6b. Social activity restriction		
1 - Participate a bit less; at least half as often as before injury (Lower GR)	49	33
2 - Participate much less; less than half as often (Upper MD)	60	44
3 - Unable to participate; rarely, if ever, take part (Lower MD)	53	40
Missing/NA	437	482
6c. Social activity change		
0 – No	12	12
1 - Yes	144	107
Missing/NA	443	480

Parameter Name	GOSEFamilyDisrupt, GOSEFamilyDisruptExtent, GOSEFamilyDisruptChange
CRF Field	7a. Has there been family or friendship disruption due to psychological problems?, 7b. What has been the extent of disruption or strain?, 7c. Were there problems with family or friends before the injury?
CRF Description	7a. Has there been family or friendship disruption due to psychological problems?, 7b. What has been the extent of disruption or strain?, 7c. Were there problems with family or friends before the injury?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

GOSE Question 7	Count at 3-month (N)	Count at 6-month (N)
7a. Family disrupt		
0 – No	325	266
1 – Yes	105	111
Missing/NA	169	222
7b. Extent of disrupt		
1 - Occasional - less than weekly (Lower GR)	42	48
2 - Frequent - once a week or more, but not tolerable (Upper MD)	37	41
3 - Constant - daily and intolerable (Lower MD)	24	20
Missing/NA	496	490
6c. Disrupt change		
0 – No	86	89
1 - Yes	15	18
Missing/NA	498	492

Parameter Name	GOSEOtherCurrentProb, GOSEOtherCurrentProbWorse
CRF Field	8a. Are there any other current problems relating to the injury which affect daily life?, 8b. Were similar problems present before the injury?
CRF Description	8a. Are there any other current problems relating to the injury which affect daily life?, 8b. Were similar problems present before the injury?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

GOSE Question 8	Count at 3-month (N)	Count at 6-month (N)
8a. Other current problems		
0 – No (upper GR)	154	140
1 - Yes (lower GR)	276	239
Missing/NA	169	220
8b. Problems before		
0 – No	381	334
1 - Yes	16	17
Missing/NA	202	248

Parameter Name	GOSEEpilepsyFits, GOSEEpilepsyRisk
CRF Field	Since the injury has the head injured person had any epileptic fits?, Have they been told that they are currently at risk of developing epilepsy?
CRF Description	Since the injury has the head injured person had any epileptic fits?, Have they been told that they are currently at risk of developing epilepsy?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

GOSE Epilepsy	Count at 3-month (N)	Count at 6-month (N)
Any epileptic fits		
0 – No	409	359
1 - Yes	17	20
Missing/NA	173	220
Epilepsy risk		
0 – No	359	317
1 - Yes	66	62
Missing/NA	174	220

Parameter Name	GOSEOutcomeFactor
CRF Field	What is the most important factor in outcome?
CRF Description	What is the most important factor in outcome?
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

GOSE Outcome Factor	Count at 3-month (N)	Count at 6-month (N)
1 - Effects of head injury	281	252
2 - Effects of illness or injury to another part of the body	48	19
3 -A mixture of these	102	107
Missing/NA	168	221

Parameter Name	GOSEScore
CRF Field	
CRF Description	
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

GOSE Score	Count at 3-month (N)	Count at 6-month (N)
1-Dead	25	28
2-Vegetative State (VS)	2	1
3-Lower Severe Disability (Lower SD)	22	17
4-Upper Severe Disability (Upper SD)	20	11
5-Lower Moderate Disability (Lower MD)	53	48
6-Upper Moderate Disability (Upper MD)	72	69
7-Lower Good Recovery (Lower GR)	133	114
8-Upper Good Recovery (Upper GR)	129	127
Missing/NA	143	184

Parameter Name	FIMEating, FIMGrooming, FIMBathing
CRF Field	
CRF Description	Eating, Grooming, Bathing
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 133 patients

Count at 6-month	Eating (N)	Grooming (N)	Bathing (N)
0 - Not done at all	1	1	1
1 - Total assistance (client 0%+)	0	1	2
2 - Maximal assistance (client 25%+)	1	0	1
3 - Moderate assistance (client 50%+)	0	0	0
4 - Minimal assistance (client 75%+)	0	0	2
5 - Supervision	4	1	0
6 - Modified independence	3	0	0
7 - Complete independence	104	110	107
Missing/NA	486	486	486

Parameter Name	FIMDressingUpperBody, FIMDressingLowerBody, FIMToileting
CRF Field	
CRF Description	Dressing- upper body, Dressing- lower body, Toileting
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 133 patients

Count at 6-month	Dressing- upper body (N)	Dressing- lower body (N)	Toileting (N)
0 - Not done at all	1	1	1
1 - Total assistance (client 0%+)	1	1	1
2 - Maximal assistance (client 25%+)	0	0	0
3 - Moderate assistance (client 50%+)	1	1	1
4 - Minimal assistance (client 75%+)	1	3	0
5 - Supervision	1	1	0
6 - Modified independence	1	1	1
7 - Complete independence	107	105	109
Missing/NA	486	486	486

Parameter Name	FIMBladder, FIMBowelManagement, FIMBedChairWheelchair
CRF Field	
CRF Description	Bladder management, Bowel management, Bed, chair, wheelchair
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 133 patients

Count at 6-month	Bladder (N)	Bowel (N)	Bed, chair, wheelchair (N)
0 - Not done at all	1	1	1
1 - Total assistance (client 0%+)	1	1	1
2 - Maximal assistance (client 25%+)	0	0	0
3 - Moderate assistance (client 50%+)	0	0	1
4 - Minimal assistance (client 75%+)	0	0	0
5 - Supervision	0	0	0
6 - Modified independence	0	1	3
7 - Complete independence	111	110	107
Missing/NA	486	486	486

Parameter Name	FIMToilet, FIMTubShower, FIMWalk
CRF Field	
CRF Description	Toilet, Tub, shower, Walk
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 133 patients

Count at 6-month	Toilet (N)	Tub, shower (N)	Walk (N)
0 - Not done at all	1	2	1
1 - Total assistance (client 0%+)	1	1	1
2 - Maximal assistance (client 25%+)	0	0	2
3 - Moderate assistance (client 50%+)	1	1	0
4 - Minimal assistance (client 75%+)	0	1	0
5 - Supervision	0	0	1
6 - Modified independence	2	2	8
7 - Complete independence	108	106	100
Missing/NA	486	486	486

Parameter Name	FIMStairs, FIMComprehension, FIMExpression
CRF Field	
CRF Description	Stairs, Comprehension (auditory), Expression (verbal)
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 133 patients

Count at 6-month	Stairs (N)	Comprehension (N)	Expression (N)
0 - Not done at all	4	1	1
1 - Total assistance (client 0%+)	0	0	0
2 - Maximal assistance (client 25%+)	0	0	0
3 - Moderate assistance (client 50%+)	0	1	2
4 - Minimal assistance (client 75%+)	1	2	0
5 - Supervision	2	1	0
6 - Modified independence	10	4	5
7 - Complete independence	96	104	105
Missing/NA	486	486	486

Parameter Name	FIMSocialInteraction, FIMProblemSolving, FIMMemory
CRF Field	
CRF Description	Social interaction, Problem solving, Memory
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	6-month result available for 133 patients

Count at 6-month	Social interaction (N)	Problem solving (N)	Memory (N)
0 - Not done at all	1	1	1
1 - Total assistance (client 0%+)	0	0	0
2 - Maximal assistance (client 25%+)	0	0	1
3 - Moderate assistance (client 50%+)	1	2	13
4 - Minimal assistance (client 75%+)	2	5	2
5 - Supervision	0	5	3
6 - Modified independence	3	7	8
7 - Complete independence	106	93	85
Missing/NA	486	486	486

Parameter Name	NeuroTimeSinceInj
CRF Field	Time Since Injury
CRF Description	Time Since Injury
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Time of assessment-Time of injury
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Time Since Injury	3-month (hours)	6-month (hours)
N	421	375
Mean	97.42	192.31
Median	94.55	185.90
Min	69.60	157.97
Max	364.97	349.95
SD	18.73	23.00
Out of range (expired)	2	4
Missing/NA	178	224

Parameter Name	NeuroPhysHeadache, NeuroPhysNausea, NeuroPhysVomiting, NeuroPhysBalanceProbl, NeuroPhysDizziness
CRF Field	
CRF Description	Headache, Nausea, Vomiting, Balance Problems, Dizziness
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Physical (1)	Count at 3-month (N)	Count at 6-month (N)
Headache		
0 – No	286	233
1 - Yes	154	149
Missing/NA	159	217
Nausea		
0 – No	380	315
1 - Yes	60	68
Missing/NA	159	216
Vomiting		
0 – No	412	352
1 - Yes	28	31
Missing/NA	159	216
Balance Problems		
0 – No	302	259
1 - Yes	137	123
Missing/NA	160	217
Dizziness		
0 – No	306	243
1 - Yes	134	139
Missing/NA	159	217

Parameter Name	NeuroPhysVisualProbl, NeuroPhysFatigue, NeuroPhysLightSensitivity, NeuroPhysNoiseSensitivity, NeuroPhysNumbnessTingling
CRF Field	
CRF Description	Visual Problems, Fatigue, Sensitivity to Light, Sensitivity to Noise, Numbness/Tingling
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Physical (2)	Count at 3-month (N)	Count at 6-month (N)
Visual Problems		
0 – No	352	284
1 - Yes	88	98
Missing/NA	159	217
Fatigue		
0 – No	268	208
1 - Yes	172	174
Missing/NA	159	217
Sensitivity to Light		
0 – No	360	299
1 - Yes	79	84
Missing/NA	160	216
Sensitivity to Noise		
0 – No	363	289
1 - Yes	77	94
Missing/NA	159	216
Numbness/Tingling		
0 – No	328	264
1 - Yes	112	117
Missing/NA	159	218

Parameter Name	NeuroSleepDrowsiness, NeuroSleepSleepingLess, NeuroSleepSleepingMore, NeuroSleepTroubleFallingAsleep
CRF Field	
CRF Description	Drowsiness, Sleeping less than usual, Sleeping more than usual, Trouble falling asleep
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Sleep	Count at 3-month (N)	Count at 6-month (N)
Drowsiness		
0 – No	304	243
1 - Yes	136	139
Missing/NA	159	217
Sleeping less than usual		
0 – No	342	272
1 - Yes	98	110
Missing/NA	159	217
Sleeping more than usual		
0 – No	352	294
1 - Yes	88	88
Missing/NA	159	217
Trouble falling asleep		
0 – No	334	252
1 - Yes	106	131
Missing/NA	159	217

Parameter Name	NeuroCognitiveFoggy, NeuroCognitiveSlowedDown, NeuroCognitiveDiffConcentrating, NeuroCognitiveDiffRemembering
CRF Field	
CRF Description	Feeling mentally foggy, Feeling slowed down, Difficulty concentrating, Difficulty remembering
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Cognitive	Count at 3-month (N)	Count at 6-month (N)
Feeling mentally foggy		
0 – No	300	247
1 - Yes	140	135
Missing/NA	159	217
Feeling slowed down		
0 – No	298	241
1 - Yes	142	141
Missing/NA	159	217
Difficulty concentrating		
0 – No	299	218
1 - Yes	141	164
Missing/NA	159	217
Difficulty remembering		
0 – No	250	187
1 - Yes	189	195
Missing/NA	159	217

Parameter Name	NeuroEmotionalIrritability, NeuroEmotionalSadness, NeuroEmotionalMoreEmotional, NeuroEmotionalNervousness
CRF Field	
CRF Description	Irritability, Sadness, More emotional, Nervousness
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Emotional	Count at 3-month (N)	Count at 6-month (N)
Irritability		
0 – No	305	220
1 - Yes	134	162
Missing/NA	160	217
Sadness		
0 – No	341	253
1 - Yes	98	129
Missing/NA	160	217
More emotional		
0 – No	328	262
1 - Yes	112	120
Missing/NA	159	217
Nervousness		
0 – No	320	254
1 - Yes	120	128
Missing/NA	159	217

Parameter Name	NeuroWorsenPhysActivity, NeuroWorsenCognitiveActivity
CRF Field	
CRF Description	Physical activity, Cognitive activity
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Worsen	Count at 3-month (N)	Count at 6-month (N)
Physical activity		
0 – No	329	294
1 - Yes	109	88
Missing/NA	161	217
Cognitive activity		
0 – No	319	265
1 - Yes	118	118
Missing/NA	162	216

Parameter Name	NeuroOverallRating
CRF Field	
CRF Description	How different is the person acting compared to his/her usual self?
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Overall Rating	Count at 3-month (N)	Count at 6-month (N)
1-Normal	154	126
2	109	97
3	80	67
4	42	48
5	29	22
6-Very Different	25	22
Missing/NA	160	217

Parameter Name	PostTimeSinceInj
CRF Field	Time Since Injury
CRF Description	Time Since Injury
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Time of assessment-Time of injury
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	Some records are at the patient death time and not the follow-up.

Time Since Injury	3-month (hours)	6-month (hours)
N	439	245
Mean	95.24	186.25
Median	94.14	184.51
Min	1.63	2.04
Max	162.31	349.87
SD	17.14	29.50
Out of range	0	0
Missing/NA	160	354

Parameter Name	PostPatientOutcome
CRF Field	Patient Outcome
CRF Description	Patient Outcome
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Patient Outcome	Count at 3-month (N)	Count at 6-month (N)
0 - Dead	19	14
1- Alive	442	388
Missing/NA	138	197

Parameter Name	PostCauseOfDeath, *PostCauseOfDeathOther*
CRF Field	Cause Of Death, *Other Cause Of Death*
CRF Description	Cause Of Death, *Other Cause Of Death*
CRF Input Type	Checkbox , *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Cause Of Death	Count at 3-month (N)	Count at 6-month (N)
1 - Head injury/initial injury	12	8
2 -Head injury/secondary intracranial damage	0	0
3 - Systemic trauma	0	0
4 - Medical complications	1	1
5 - Other	2	0
Missing/NA	584	590
Other Cause Of Death	*2*	*0*

Parameter Name	PostPatientResidenceStatus
CRF Field	Patient Residence
CRF Description	Patient Residence
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Patient Residence	Count at 3-month (N)	Count at 6-month (N)
0	0	10
1 - On date of assessment:	437	380
2 -On date of death:	15	0
Missing/NA	147	209

Parameter Name	PostPatientResidence, *PostPatientResidenceOther*
CRF Field	Residence, *Other Residence*
CRF Description	Residence, *Other Patient Residence (not in dropdown list)*
CRF Input Type	Radio, *Text*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Residence	Count at 3-month (N)	Count at 6-month (N)
1 - Home	396	349
2 - Hospital	13	9
3 - Rehab center	8	3
4 - Nursing home	6	9
5 - Other	25	15
Missing/NA	151	214
Other Patient Residence	*25*	*15*

Parameter Name	PostReturnToWork
CRF Field	Return to work/school
CRF Description	Return to work/school
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Return to work/school	Count at 3-month (N)	Count at 6-month (N)
1 - No	102	82
2 - Sheltered	1	3
3 - Partial	29	21
4 - Full	210	199
5 - N/A	100	81
6 - Unknown	1	2
Missing/NA	116	211

Parameter Name	PostFamilyStrain
CRF Field	Family Strain/disruption
CRF Description	Family Strain/disruption
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Family Strain/disruption	Count at 3-month (N)	Count at 6-month (N)
1 - None	336	268
2 - Minor	46	48
3 - Moderate	38	48
4 - Severe	19	20
Missing/NA	160	215

Parameter Name	PostMarriageEffect
CRF Field	Effect on marriage
CRF Description	Effect on marriage
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Effect on marriage	Count at 3-month (N)	Count at 6-month (N)
1 - None	206	160
2 - Separated	4	6
3 - Divorced	2	1
4 – N/A	227	215
Missing/NA	160	217

Parameter Name	PostLegalIssues
CRF Field	Is the patient currently involved with any legal issues resulting from the injuries incurred from the original incident?
CRF Description	Patient involved in legal issues resulting from incident?
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Legal Issues	Count at 3-month (N)	Count at 6-month (N)
0 - No	340	304
1 - Yes	72	70
2 – Don't know	27	11
Missing/NA	160	214

Parameter Name	PostRehab
CRF Field	Rehabilitation
CRF Description	Type of Rehabilitation
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Rehabilitation	Count at 3-month (N)	Count at 6-month (N)
1 - None	303	225
2 - Only as outpatient	59	89
3 - General rehab (inpt)	26	25
4 - TBI rehabilitation unit (inpt)	44	41
5 - General long-term care unit (inpt)	3	5
6 - Geriatric rehab unit (inpt)	3	2
Missing/NA	161	212

Parameter Name	PostRehabInterupt1Reason, PostRehabInterupt2Reason
CRF Field	Reason
CRF Description	Reason for Rehab interruption 1, Reason for Rehab interruption 2
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Reason for Rehab interruption	Interruption 1 at 3-month (N)	Interruption 2 at 3-month (N)	Interruption 1 at 6-month (N)	Interruption 2 at 6-month (N)
1 - Readmit to hospital	1	0	0	0
2 - Readmit to ICU	1	0	0	0
3 - Required surgical procedure	3	0	3	1
4 - Return to Work	0	0	0	0
5 - Other	1	1	2	1
Missing/NA	593	598	594	597

Parameter Name	PostOutPatientOngoing
CRF Field	Active Rehab Ongoing
CRF Description	Is Active Rehab still Ongoing
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Outpatient Therapy Ongoing	Count at 3-month (N)	Count at 6-month (N)
0 - No	127	108
1 - Yes	85	61
Missing/NA	387	430

Parameter Name	PostOutPatientTherapy, *PostOutPatientTherapyOther*
CRF Field	Type of Outpatient Therapy, *Other*
CRF Description	Type of Outpatient Therapy, *Other Type of Outpatient Therapy (not in dropdown list)*
CRF Input Type	Checklist
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Type of Outpatient Therapy	Count at 3-month (N)	Count at 6-month (N)
1 - Physical therapy	109	114
2 - Occupational therapy	32	34
3 - Speech therapy	29	29
4 - Therapeutic recreation	4	2
5 - Cognitive remediation	5	7
6 - Vocational services	0	1
7 - Psychological services	15	21
8 - Nursing services	9	3
9 - Comprehensive day treatment	0	0
10 - Peer mentoring	0	1
11 - Social work/Case management	12	2
12 - Independent living training	0	0
13 - Home health	1	2
14 - Other hospital unit	3	0
15	0	2
Missing/NA	468	459
Other Type of Outpatient Therapy	*15*	*14*

Parameter Name	PostOutPatientTherapyFreq
CRF Field	Frequency of outpatient therapy
CRF Description	Frequency of outpatient therapy
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Frequency of outpatient therapy	Count at 3-month (N)	Count at 6-month (N)
1 - Only follow-up; no active treatment	19	6
2 - Less than once per week	12	20
3 - Weekly	36	44
4 - 2-3 times per week	64	71
5 - Daily	2	2
Missing/NA	466	456

Parameter Name	PostOutPatientDone
CRF Field	Did the patient have any type(s) of outpatient therapy at all since discharge from the hospital?
CRF Description	Did the patient have any type(s) of outpatient therapy at all since discharge from the hospital?
CRF Input Type	Radio
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Outpatient Therapy	Count at 3-month (N)	Count at 6-month (N)
0 - No	147	182
1 - Yes	64	122
Missing/NA	388	295

Parameter Name	RPQHeadaches, RPQDizziness, RPQNausea
CRF Field	
CRF Description	Headaches, Feelings of dizziness, Nausea and/or vomiting
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	Complete assessment available for 341 patients, 2 incomplete

Count at 6-month	Headaches (N)	Dizziness (N)	Nausea (N)
0 - Not experienced at all	164	175	261
1 -No more of a problem	70	68	35
2 - A mild problem	57	63	23
3 - A moderate problem	32	26	14
4 - A severe problem	16	8	6
Missing/NA	260	259	260

Parameter Name	RPQNoiseSensitivity, RPQSleepDisturbance, RPQFatigue
CRF Field	
CRF Description	Noise sensitivity (easily upset by loud noise), Sleep disturbance, Fatigue, tiring more easily
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	Complete assessment available for 341 patients, 2 incomplete

Count at 6-month	Noise sensitivity (N)	Sleep disturbance (N)	Fatigue (N)
0 - Not experienced at all	212	165	132
1 -No more of a problem	33	40	54
2 - A mild problem	46	50	78
3 - A moderate problem	34	51	52
4 - A severe problem	14	33	23
Missing/NA	260	260	260

Parameter Name	RPQIrritable, RPQDepressed, RPQFrustrated
CRF Field	
CRF Description	Being irritable or easily angered, Feeling depressed or tearful, Feeling frustrated or impatient
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	Complete assessment available for 341 patients, 2 incomplete

Count at 6-month	Irritable (N)	Depressed (N)	Frustrated (N)
0 - Not experienced at all	153	181	151
1 -No more of a problem	58	56	60
2 - A mild problem	64	58	68
3 - A moderate problem	40	29	34
4 - A severe problem	25	14	27
Missing/NA	259	261	259

Parameter Name	RPQForgetful, RPQPoorConcentration, RPQLongerToThink
CRF Field	
CRF Description	Forgetfulness or poor memory, Poor concentration, Taking longer to think
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	Complete assessment available for 341 patients, 2 incomplete

Count at 6-month	Forgetful (N)	Poor Concentration (N)	Take Longer To Think (N)
0 - Not experienced at all	110	138	136
1 -No more of a problem	69	63	60
2 - A mild problem	72	66	68
3 - A moderate problem	64	59	49
4 - A severe problem	25	14	27
Missing/NA	259	259	259

Outcomes	Rivermead Post-concussion Symptoms Questionnaire (2)	Blurred vision/ Light sensitivity/ Double vision

Parameter Name	RPQBlurredVision, RPQLightSensitivity, RPQDoubleVision
CRF Field	
CRF Description	Blurred vision, Light sensitivity (easily upset by bright light), Double vision
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	Complete assessment available for 341 patients, 2 incomplete

Count at 6-month	Blurred vision (N)	Light sensitivity (N)	Double vision (N)
0 - Not experienced at all	231	231	281
1 -No more of a problem	36	38	26
2 - A mild problem	32	34	15
3 - A moderate problem	19	22	9
4 - A severe problem	21	14	8
Missing/NA	259	259	260

Parameter Name	RPQRestless, RPQOther1, *RPQOther1Text*, RPQOther2, *RPQOther2Text*
CRF Field	
CRF Description	Restlessness, Are you experiencing any other difficulties? 1., *Are you experiencing any other difficulties? 1. Please specify*, Are you experiencing any other difficulties? 2., *Are you experiencing any other difficulties? 2. Please specify*
CRF Input Type	Dropdown, *Text area*
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical, *Text*
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	Complete assessment available for 341 patients, 3 incomplete

Count at 6-month	Restlessness(N)	Other 1 (N)	Other 2 (N)
0 - Not experienced at all	191	3	3
1 -No more of a problem	58	2	1
2 - A mild problem	41	11	2
3 - A moderate problem	32	7	2
4 - A severe problem	18	16	4
Missing/NA	259	560	587
Please specify		*36*	*9*

Parameter Name	RPQ3Score, RPQ13Score
CRF Field	
CRF Description	RPQ-3, RPQ-13
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Sum of question 1-3, Sum of question 4-13
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	Complete assessment available for 341 patients, 2 incomplete

RPQ Score at 6-month	RPQ-3	RPQ-13
N	341	341
Mean	2.33	13.40
Median	2	11
Min	0	0
Max	11	49
SD	2.57	12.01
Out of range	0	0
Missing/NA	258	258

Parameter Name	SWLSIdeal, SWLSExcellent, SWLSSatisfied, SWLSImportant, SWLSChangeNothing
CRF Field	
CRF Description	1. In most ways my life is close to my ideal., 2. The conditions of my life are excellent., 3. I am satisfied with my life., 4. So far I have gotten the important things I want in life., 5. If I could live my life over, I would change almost nothing.
CRF Input Type	Dropdown
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Categorical
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

Count at 6-month	Q1 (N)	Q2 (N)	Q3 (N)	Q4 (N)	Q5 (N)
1- Strongly Disagree	35	43	24	24	55
2- Disagree	39	48	46	46	57
3- Slightly Disagree	44	36	38	31	44
4- Neither Agree nor Disagree	26	39	27	30	33
5- Slightly Agree	59	60	62	56	42
6- Agree	82	73	86	92	63
7- Strongly Agree	32	38	54	58	42
Missing/NA	262	262	262	262	263

Parameter Name	SWLSTotalScore
CRF Field	
CRF Description	SWLS Total Score
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	Sum of question 1-5
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

SWLS Score at 6-month	Total Score
N	337
Mean	21.47
Median	22
Min	5
Max	35
SD	7.83
Out of range (0)	2
Missing/NA	260

Parameter Name	TMTPartATime, TMTPartAErrors, TMTPartBTime, TMTPartBErrors
CRF Field	
CRF Description	Trail Making Part A Time (in secs):, Trail Making Part A # of Errors:, Trail Making Part B Time (in secs):, Trail Making Part B # of Errors:
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

TMT at 6-month	Part A Time (seconds)	Part A Number of Errors	Part B Time (seconds)	Part B Number of Errors
N	308	307	307	307
Mean	35.43	0.65	89.57	0.62
Median	31.7	0	69.8	0
Min	12	0	24.2	0
Max	135.6	8	484	8
SD	16.93	1.04	62.73	1.04
Out of range	0	0	0	0
Missing/NA	291	292	292	292

Parameter Name	WAISAgeAtTest
CRF Field	
CRF Description	Age At Time of Test:
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

WAIS IV at 6-month	Age At Time of Test (years)
N	267
Mean	41.63
Median	40
Min	18
Max	80
SD	16.47
Out of range	0
Missing/NA	332

Parameter Name	WAISCodingTotalRawScore, WAISCodingStandardScore, WAISCodingCompletionTime
CRF Field	
CRF Description	Coding Subset Total Raw Score:, Coding Subset Standard Score:, Coding Subset Completion Time (seconds):
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	Standard score 1-19
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

WAIS IV Coding Subset at 6-month	Total Raw Score	Standard Score	Completion Time (seconds)
N	302	303	267
Mean	63.22	9.50	120
Median	63	10	120
Min	15	1	120
Max	113	19	120
SD	17.73	2.96	0
Out of range	0	0	0
Missing/NA	297	296	332

Parameter Name	WAISSymbolCorrect, WAISSymbolIncorrect, WAISSymbolTotalRawScore, WAISSymbolStandardScore, WAISSymbolCompletionTime
CRF Field	
CRF Description	Symbol Search Subset Total correct:, Symbol Search Subset Total incorrect:, Symbol Search Subset Total Raw Score (# correct minus # incorrect):, Symbol Search Subset Standard Score:, Symbol Search Subset Completion Time (seconds):
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

WAIS IV Symbol Search Subset at 6-month	Total Correct	Total Incorrect	Total Raw Score	Standard Score	Completion Time (seconds)
N	305	305	305	305	268
Mean	32.70	1.02	31.68	10.30	120
Median	33	1	32	10	120
Min	7	0	5	1	120
Max	70	7	70	19	120
SD	9.90	1.31	9.96	3.39	0
Out of range	0	0	0	0	5
Missing/NA	294	294	294	294	326

Outcomes

Trail Making Test
and WAIS IV

WAIS IV
Processing Speed
Index Summary

Parameter Name	WAISSumOfScaledScores, WAISSymbolProcessingSpeedIndex, WAISProcessingSpeedIndexPercentileRank
CRF Field	
CRF Description	Sum of Scaled Scores:, PSI Composite Score:, PSI Percentile Rank:
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

WAIS IV PSI Summary at 6-month	Sum of Scaled Scores	PSI Composite Score	PSI Percentile Rank
N	303	303	303
Mean	19.82	99.46	48.75
Median	20	100	50
Min	2	50	0.1
Max	38	150	99.9
SD	5.82	15.77	29.00
Out of range	0	0	0
Missing/NA	296	296	296

| Outcomes | Trail Making Test and WAIS IV | WAIS IV PSI Confidence Interval |

Parameter Name	WAISProcessingSpeedCI90Lower, WAISProcessingSpeedCI90Upper, WAISProcessingSpeedCI95Lower, WAISProcessingSpeedCI95Upper
CRF Field	
CRF Description	PSI Confidence Interval (90%): From, PSI Confidence Interval (90%): To, PSI Confidence Interval (95%): From, PSI Confidence Interval (95%): To
CRF Input Type	Text area
NIND 2.0 CDE ID	
NIND 2.0 CDE Name	
IMPACT 1.5 CDE	
Variable Type	Numerical
Calculation Rule	
Permissible Range	
Recommended Interpretation for missing/NA values	Not applicable/Not done/Expired, Unknown/Not reported
Comments	

WAIS IV PSI Confidence Interval at 6-month	90% from	90% to	95% from	95% to
N	303	303	303	303
Mean	92.21	106.54	91.15	107.84
Median	93	107	92	108
Min	3	62	47	63
Max	138	152	137	153
SD	15.10	14.31	14.20	14.20
Out of range	0	0	0	0
Missing/NA	296	296	296	296

Original Articles

Diffusion Tensor Imaging for Outcome Prediction in Mild Traumatic Brain Injury: A TRACK-TBI Study

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Abstract

We evaluated 3T diffusion tensor imaging (DTI) for white matter injury in 76 adult mild traumatic brain injury (mTBI) patients at the semiacute stage (11.2 ± 3.3 days), employing both whole-brain voxel-wise and region-of-interest (ROI) approaches. The subgroup of 32 patients with any traumatic intracranial lesion on either day-of-injury computed tomography (CT) or semiacute magnetic resonance imaging (MRI) demonstrated reduced fractional anisotropy (FA) in numerous white matter tracts, compared to 50 control subjects. In contrast, 44 CT/MRI-negative mTBI patients demonstrated no significant difference in any DTI parameter, compared to controls. To determine the clinical relevance of DTI, we evaluated correlations between 3- and 6-month outcome and imaging, demographic/socioeconomic, and clinical predictors. Statistically significant univariable predictors of 3-month Glasgow Outcome Scale-Extended (GOS-E) included MRI evidence for contusion (odds ratio [OR] 4.9 per unit decrease in GOS-E; $p = 0.01$), ≥ 1 ROI with severely reduced FA (OR, 3.9; $p = 0.005$), neuropsychiatric history (OR, 3.3; $p = 0.02$), age (OR, 1.07/year; $p = 0.002$), and years of education (OR, 0.79/year; $p = 0.01$). Significant predictors of 6-month GOS-E included ≥ 1 ROI with severely reduced FA (OR, 2.7; $p = 0.048$), neuropsychiatric history (OR, 3.7; $p = 0.01$), and years of education (OR, 0.82/year; $p = 0.03$). For the subset of 37 patients lacking neuropsychiatric and substance abuse history, MRI surpassed all other predictors for both 3- and 6-month outcome prediction. This is the first study to compare DTI in individual mTBI patients to conventional imaging, clinical, and demographic/socioeconomic characteristics for outcome prediction. DTI demonstrated utility in an inclusive group of patients with heterogeneous backgrounds, as well as in a subset of patients without neuropsychiatric or substance abuse history.

Key words: axonal injury; computed tomography; diffusion tensor imaging; magnetic resonance imaging; traumatic brain injury

Introduction

MILD TRAUMATIC BRAIN INJURY (mTBI) comprises 75% of the estimated 1.7 million patients who seek medical attention annually in the United States for acute head injury.[1] The most widely accepted definitions of mTBI[2–4] include patients with 1) nonpenetrating head trauma resulting in one or more of the following: confusion/disorientation; loss of consciousness (LOC) < 30 min in duration, post-traumatic amnesia (PTA) < 24 h in duration; and transient focal neurological signs or seizure and 2) Glasgow Coma

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Scale (GCS) score of 13–15 upon acute medical evaluation. Previous studies suggest that many mTBI patients have significant alterations in cognitive and/or behavioral functioning within weeks to months of injury, and approximately 15–20% have persistent measurable deficits at 1 year.[5–12] There is also growing recognition that current classification schemes for mTBI/concussion based solely on GCS, PTA, and LOC are severely limited, with small *mean* effect sizes in long-term impairment obscuring differences among diverse subgroups of mTBI patients with very different prognoses.[13,14] To date, there remains a need for practical, widely available clinical, laboratory, and/or imaging markers that identify patients who will experience persistent dysfunction after mTBI.

Many studies have reported changes in white matter diffusion tensor imaging (DTI) parameters in acute, subacute, and chronic time frames after mTBI.[15–37] The clinical significance of acute traumatic intracranial findings on conventional computed tomography (CT) and magnetic resonance neuroimaging has also been explored.[38,39] However, little is known about the relationship between conventional CT and magnetic resonance imaging (MRI) findings and DTI evidence of white matter injury within the mTBI spectrum. In addition, there has been little exploration of the use of acute or subacute DTI data for prediction of outcome in individual patients, after controlling for demographic, clinical, and CT and conventional MRI predictors. Although group differences in DTI parameters between mTBI patients and controls have been demonstrated, no consensus yet exists on the practical application of these techniques to outcome prediction in the individual patient. Finally, nearly all previous studies of DTI in mTBI have excluded patients with any history of substance abuse or other neuropsychiatric disorder, and the generalizability of their results to the general mTBI population is uncertain.

In this study, we used both whole-brain voxel-wise and region-of-interest (ROI) analyses to assess for an association between CT and conventional MRI abnormalities and early DTI measures of white matter integrity after mTBI. To determine the clinical relevance, if any, of DTI measures to outcome in mTBI, we then assessed for correlations between DTI measures and 3- and 6-month outcome. We compared the strengths of these correlations to those between outcome and conventional imaging, demographic, and clinical predictors previously found to influence outcome, based on the assumption that any utility of DTI in outcome prediction would require a *differential* increase in predictive power over predictors that are routinely assessed in current practice. To our knowledge, this is the first study to compare the relative strengths of DTI features in individual mTBI patients to conventional MRI, CT, clinical, demographic, and socioeconomic features for the prediction of 3- and 6-month outcome. In order to maximize the generalizability of study conclusions, we analyzed both an inclusive sample of 76 mTBI patients with very few exclusion criteria, as well as a subset of 37 patients with no significant drug, alcohol, or neuropsychiatric history.

Methods

Study population

mTBI patients were enrolled at San Francisco General Hospital (SFGH; San Francisco, CA) as part of the prospective multi-center TRACK-TBI (Transforming Research and Clinical Knowledge in Traumatic Brain Injury) pilot study.[40] The primary inclusion criterion for the TRACK-TBI pilot study was performance of noncontrast head CT to assess for evidence of acute TBI within 24 h of injury, based on criteria from the American College of Emergency Physicians/Centers for Disease Control (ACEP/CDC) evidence-based joint practice guideline (Supplementary Table S1) (see online

supplementary material at http://www.liebertpub.com).[41] The TRACK-TBI pilot study exclusion criteria were limited and consisted of nonfluency in English, contraindication to MRI, pregnancy, and current incarceration/legal detention or placement on psychiatric hold.[40]

For the current study of DTI of mTBI, additional inclusion criteria were GCS 13–15 upon emergency department (ED) arrival, LOC <30 min, PTA duration <24 h, and age 18–55 years (inclusive); an additional exclusion criterion was any reported history of earlier TBI resulting in LOC >5 min. Of 190 mTBI patients in the 18- to 55-year age range enrolled at SFGH for the TRACK-TBI pilot study, 87 patients did not undergo brain MRI. Of the remaining 103 patients, 18 reported a history of earlier TBI with LOC >5 min or of unknown duration; 5 had a technically inadequate brain MRI exam (because of motion or, in 1 case, because of severe susceptibility artifact resulting from a metallic shunt valve within the scalp); 1 patient had an extensive area of encephalomalacia likely the result of an earlier TBI; 1 had an acute large-territory infarct resulting from acute traumatic arterial dissection; and 2 were excluded because their performance on the Trail Making Test (TMT) B and other outcome measures were extreme outliers, despite a GCS of 15 upon ED arrival, no LOC or PTA, and no CT or conventional MRI evidence of traumatic intracranial injury. The final patient group for the current study therefore consisted of 76 mTBI patients enrolled at SFGH who underwent brain MRI on a single 3T MRI scanner within 3 weeks of TBI. In addition, a control group consisted of 50 healthy subjects, ages 18–55 years, with no self-reported history of drug or alcohol abuse, neuropsychiatric illness, or earlier TBI, who underwent brain MRI on the same 3T scanner over the same time period, employing the same MRI protocol and software version. All study protocols were approved by the University of California at San Francisco Institutional Review Board, and all patients and control subjects or their legal representatives gave written informed consent.

Table 1 summarizes demographic, socioeconomic, and clinical characteristics of participants and control subjects. We assessed for statistically significant differences in demographic, socioeconomic, and clinical features at $p < 0.05$ among the following groups: 1) CT/MRI-positive patients, defined as patients with any acute traumatic intracranial lesion or depressed skull fracture on day-of-admission CT or semiacute 3T MRI; 2) CT/MRI-negative patients, defined as patients without any such abnormality; and 3) control subjects. We used analysis of variance (ANOVA) for scale variables without significant deviation from a normal distribution, and Mann-Whitney U test for ordinal and non-normal variables. Differences in nominal variables were assessed by chi-square (χ^2) test for independence or by Fisher's exact test for nominal variables with an expected count of fewer than 5 subjects in any cell. All statistical analyses were performed using SPSS Statistics (version 21; SPSS, Inc., Chicago, IL).

CT and MRI protocols

CT was performed within 2 h 42 min ± 3 h 9 min of TBI. MRI was performed within 11.2 ± 3.3 days (range, 5–18) postinjury. All CT exams were performed on a GE Lightspeed 64-row-detector CT scanner, and all MRI exams were performed on the same 3T GE Signa EXCITE scanner equipped with an eight-channel phased-array head radiofrequency coil (GE Healthcare, Waukesha, WI), using the same scanner software version. Whole-brain DTI was performed with a multi-slice single-shot spin echo echoplanar pulse sequence (echo time [TE] = 63 ms; repetition time [TR] = 14 sec) using 55 diffusion-encoding directions, isotropically distributed over the surface of a sphere with electrostatic repulsion, acquired at b = 1000 sec/mm^2, seven acquisitions at b = 0 sec/mm^2, 72 interleaved slices of 1.8-mm thickness each with no gap between slices, a 128 × 128 matrix, and a field of view (FOV) of 230 × 230 mm.

TABLE 1. DEMOGRAPHIC, SOCIOECONOMIC, AND CLINICAL PREDICTORS FOR 76 MTBI PATIENTS AND 50 CONTROL SUBJECTS

Predictors	CT/MRI-negative mTBI (no acute traumatic intracranial abnormality or depressed skull fracture on CT and/or conventional MRI) (44 subjects)	CT/MRI-positive mTBI (acute traumatic intracranial abnormality and/or depressed skull fracture on CT and/or conventional MRI) (32 subjects)	Controls (50 subjects)	Analysis for group differences among CT/MRI-negative mTBI, CT/MRI-positive mTBI, and control subjects
Demographic and socioeconomic				
Age (years, mean ± standard deviation)	31.2 ± 9.5	33.9 ± 12.0	28.7 ± 9.2	ANOVA $F_{(2,123)}=2.6$; $p=0.08$
Education (years, mean ± standard deviation)	14.8 ± 2.8	14.6 ± 2.1	15.7 ± 1.6	$F_{(2,109)}=2.6$; $p=0.08$
Gender: male/female (% male)	27/17 (61%)	23/9 (72%)	32/18 (64%)	χ^2 test for independence χ^2 (2; $n=126$)=0.9; $p=0.65$
Unemployed[a] : yes/no (% yes)	5/39 (11%)	6/25 (19%)	Unknown	Fisher's exact test $p=0.51$
Handedness[b] (right/left/ambidextrous)	39/4/1	27/4/1	48/1/0	$p=0.14$
Clinical				
Neuropsychiatric history: yes/no (% yes)	12/32 (27%)[d]	6/26 (19%)[d]	0/50 (0%)[e]	χ^2 test for independence χ^2 (2; $n=126$)=14.9; $p=0.0004$
History of drug or alcohol problem: yes/no (% yes)	21/23 (48%)[f]	14/18 (44%)[f]	0/50 (0%)[g]	χ^2 (2; $n=126$)=32.0; $p<10^{-6}$
LOC: yes, up to 30 min/no (% yes)	28/16 (64%)	23/9 (72%)	N/A	χ^2 (1; $n=76$)=0.6; $p=0.47$
PTA: yes/no (% yes)	26/18 (59%)	25/7 (78%)	N/A	χ^2 (1; $n=76$)=3.0; $p=0.09$
PTA duration[c]	None 18 <1 min 6 1–29 min 14 30–59 min 3 1–24 h 3	None 7 <1 min 1 1–29 min 11 30–59 min 5 1–24 h 4	N/A	Mann-Whitney U test CT/MRI-negative median PTA duration <1 min; CT/MRI-positive median PTA duration 1–29 min; U=440; $z=-2.1$; $p=0.03$
GCS (15/14/13)	36/7/1	20/11/1	N/A	Fisher's exact test $p=0.13$
Previous TBI with LOC up to 5 min: yes/no (% yes)	15/29 (34%)[h]	8/24 (25%)[h]	0/50 (0%)[i]	$p=0.000003$

Gray shaded boxes indicate statistically significant difference at $p<0.05$.
[a]One CT/MRI-positive mTBI patient with unknown employment status was not included in this analysis.
[b]One control with unknown handedness was not included in this analysis.
[c]Four CT/MRI-positive mTBI patients with PTA <24h, but not otherwise specified, were not included in this analysis.
[d-i]Each superscript denotes a subset of participants whose proportions do not significantly differ from each other at $p<0.05$ by Pearson's χ^2 test (or Fisher's exact test when expected cell count <5).
mTBI, mild traumatic brain injury; ANOVA, analysis of variance; GCS, Glasgow Coma Scale; PTA, post-traumatic amnesia; LOC, loss of consciousness; N/A, not available.

Parallel imaging was employed using the array spatial sensitivity encoding technique (ASSET) with an acceleration factor of 2.

The following conventional 3T MRI sequences were also performed: 1) axial three-dimensional (3D) inversion recovery fast spoiled gradient recalled echo T1-weighted images (TE = 1.5 ms; TR = 6.3 ms; inversion time [TI] = 400 ms; flip angle, 15 degrees) with 230-mm FOV, 156 contiguous partitions (1.0-mm) at 256×256 matrix; 2) axial T2-weighted fluid-attenuated inversion recovery images (TE = 126 ms; TR = 10 sec; TI = 2200 ms) with 220 mm FOV, 47–48 contiguous slices (3.0-mm) at 256×256 matrix; and 3) axial magnetization-prepared gradient echo T2*-weighted images (TE = 15 ms; TR = 500 ms; flip angle 20 degrees) with 220×170 mm FOV and 47–48 contiguous slices (3.0-mm) at 256×192 matrix.

Neuroradiologist evaluation of CT and MRI studies for acute traumatic abnormalities

Each patient's head CT upon ED presentation and early brain MRI (11.2 ± 3.3 days postinjury) was characterized using the TBI common data elements (TBI-CDE). The TBI-CDEs are consensus-based recommendations for data collection, data definitions, and best practices in TBI research established jointly by the National Institute of Neurological Disorders and Stroke (NINDS), Defense Centers of Excellence, National Institute on Disability and Rehabilitation Research, and Veterans Administration.[42–44] Each CT and MRI was anonymized and reviewed by a board-certified neuroradiologist blinded to demographic, socioeconomic, and clinical data, except gender and age, and without concurrent access to the patient's other head imaging studies or 3- and 6-month outcome measures.

mTBI patients were divided into two subgroups: 1) CT/MRI positive, defined as patients with any acute traumatic intracranial lesion (epidural hematoma [EDH], subdural hematoma [SDH], subarachnoid hemorrhage [SAH], contusion, or evidence of traumatic axonal injury) and/or depressed skull fracture on either CT or MRI, and 2) CT/MRI negative, defined as patients without any such abnormality. Most previous studies of ''complicated'' mTBI, including Williams and colleagues,[38] demonstrated poorer neuropsychiatric test performance based solely on CT findings (presence of any acute intracranial hemorrhage or depressed skull fracture). Our dichotomization of mTBI patients according to presence of abnormalities on *either* CT or MRI is based on more recent work that demonstrated poorer 3-month outcome associated with early MRI intracranial abnormalities, whether or not visible on CT.[39]

Diffusion tensor image processing

Nonbrain tissue was eliminated from the diffusion-weighted and 3D T1-weighted images using the Functional MRI of the Brain (FMRIB, Oxford University, Oxford, UK) Brain Extraction Tool.[45] Diffusion-weighted images were corrected for eddy currents and registered to the $b = 0 \sec/mm^2$ volume using the FMRIB Linear Image Registration Tool. A diffusion tensor model was constructed using the FMRIB DTIFit algorithm[46] to yield fractional anisotropy (FA), mean diffusivity (MD), axial diffusivity (AD), and radial diffusivity (RD) at each voxel. Tract-based spatial statistics (TBSS)[47] were used to align each subject's FA data to a white matter skeleton, after low FA values below a threshold of 0.25 were excluded to limit voxels to the white matter.

Voxel-wise nonparametric statistical comparison between 76 mTBI patients and 50 controls was performed using the FMRIB Software Library (FSL) randomise algorithm based on permutation testing, with corrections for multiple voxel-wise comparisons using threshold-free cluster enhancement (TFCE).[48] Anatomic locations of voxel clusters with statistically significant differences in FA, MD, RD, or AD between mTBI and control groups at $p < 0.05$ were

determined. This analysis was also used to compare the subgroup of 32 CT/MRI-positive patients to the 50 controls and also the subgroup of 44 CT/MRI-negative mTBI patients to the 50 controls.

In addition to the whole-brain voxel-wise approach, we performed a complementary ROI analysis to address the possibility that a whole-brain, data-driven approach might not be sufficiently sensitive to reveal white matter injury because of possibly significant spatial heterogeneity of white matter injury across mTBI subjects. Twenty-seven white matter ROIs were delineated by the intersection of the Johns Hopkins University (Baltimore, MD) ICBM-DTI-81 White Matter Labeled Atlas[49] and the reference white matter skeleton. These consisted of the anterior corona radiata, superior corona radiata, posterior corona radiata, anterior limb of internal capsule, posterior limb of internal capsule, external capsule, superior longitudinal fasciculus, sagittal striatum, ventral cingulum (parahippocampal gyrus), dorsal cingulum (cingulate gyrus), inferior fronto-occipital fasciculus, and superior fronto-occipital fasciculus, each on the left and right; and also the body, genu, and splenium of the corpus callosum. The FA, MD, AD, and RD within each of these 27 ROIs in each patient and control subject were determined. For each ROI, the mean and standard deviation (SD) of the FA within the group of 50 control subjects was calculated. Similarly, for each ROI, the mean and SD for each of the other DTI measures (MD, AD, and RD) in the group of 50 control subjects were calculated. For each of the 76 mTBI patients and 50 control subjects, an abnormal ROI was then defined as one in which a DTI measure (FA, MD, AD, or RD) was more than 2.2 SDs below or above the control-group mean, based on the distribution of the DTI measure within the 50 control patients alone.

Outcome measures

Outcome measures included the Extended Glasgow Outcome Scale (GOS-E) at 3 and 6 months postinjury, the Rivermead Postconcussion Symptoms Questionnaire (RPQ), California Verbal Learning Test–Second Edition (CVLT-II), Wechsler Adult Intelligence Scale–Fourth Edition, Processing Speed Index (WAIS-IV PSI), and Trail Making Tests A and B (TMT A and TMT B) at 6 months. The GOS-E was obtained at 3 and 6 months postinjury through structured interview with each participant by research assistants trained to uniformly assess the GOS-E. Modeled after the 5-point Glasgow Outcome Scale (GOS), the 8-point GOS-E provides better discrimination among more subtle aspects of disability within mild-to-moderate, rather than mild-to-severe, TBI and is a well-validated, widely employed measure of global function after mTBI.[50] The TMT A and B are tests of visual attention, visual-motor coordination, task switching, and executive function.[51,52] WAIS-IV PSI is a test of perceptual processing speed with additional contribution from working memory.[53,54] The CVLT-II is a test of verbal learning and memory and was used in place of the TBI CDE Rey Auditory Verbal Learning Test because of recent revision of the CVLT with demonstration of improved psychometric properties.[55,56] The RPQ consists of 16 symptoms frequently reported after mTBI.[57,58] The first three symptoms, denoted RPQ-3, are more physical symptoms (headaches, dizziness, and nausea/vomiting) typically experienced immediately after the TBI event, whereas the other 13 symptoms (denoted RPQ-13) are more psychosocial in nature (hyperacusis, sleep disturbances, fatigue, irritability, depressed mood, frustration, forgetfulness, poor concentration, requiring longer times to think, blurred vision, light sensitivity, double vision, and restlessness) and have been shown to occur later in the clinical course after mTBI.[59,60]

We assessed for statistically significant group differences in each outcome measure between CT/MRI-positive and -negative mTBI patients. The CVLT-II, WAIS-IV PSI, and TMT A and B scores were converted to normative scores for age, and ANOVA was used to test for group differences in these variables between CT/MRI-positive and -negative mTBI patients at $p < 0.05$. Mann-

Whitney U test was used to assess for group differences in the 3-month GOS-E, 6-month GOS-E, RPQ-3, and RPQ-13 at $p < 0.05$. All statistical analyses were performed using SPSS Statistics (version 21).

Spearman's correlation and ordinal logistic regression analyses

We calculated Spearman's correlation coefficients between each outcome measure and each of 11 demographic (age, gender), socioeconomic (employment status, number of years of formal education), and clinical (history of major neuropsychiatric diagnosis, history of drug or alcohol abuse, GCS upon ED arrival, any PTA, PTA duration, any LOC, any history of mTBI with LOC duration not exceeding 5 min) predictors, 5 noncontrast head CT features (calvarial or skull base fracture, EDH, SDH, SAH, contusion), and 3 brain MRI features (contusion, hemorrhagic axonal injury, or evidence of white matter injury on DTI ROI analysis). We used Spearman's correlation, rather than its parametric counterpart, Pearson's product-moment correlation, because of the nominal or ordinal nature and/or non-normal distribution of most of these variables. We then performed multivariable logistic or linear regression of each outcome measure upon all predictors with which the outcome measure had demonstrated a statistically significant pairwise Spearman's correlation. For both Spearman's correlation and the regression analyses, the CVLT-II, WAIS-IV PSI, and TMT A and B test scaled or z-scores, as well as binary outcome variables corresponding to performance worse or better than 2 SDs worse than the normative score as determined by previous studies,[52,54,55] were included as outcome variables. For the ordinal logistic regression analyses, tests for parallel lines were performed and confirmed the proportional odds assumption for each analysis. These statistical analyses were performed using SPSS Statistics (version 21).

Results

Study population characteristics

Table 1 summarizes demographic, socioeconomic, and clinical characteristics of participants. There were no statistically significant differences among CT/MRI-positive, CT/MRI-negative, and control subjects in age, number of years of formal education, gender, or handedness. Employment status was unknown for control subjects, but there was no difference at $p < 0.05$ between CT/MRI-positive and -negative patients. Among the clinical variables, rates of major neuropsychiatric diagnosis, history of drug or alcohol abuse, and history of previous mTBI with LOC up to 5 min were significantly higher in CT/MRI-negative and -positive mTBI pa-

tients than in control subjects, but were not statistically different between CT/MRI-negative and -positive patients. (Patients with a history of any previous TBI with LOC > 5 min had been excluded from the study.) PTA duration was longer in CT/MRI-positive patients (median PTA duration, 1–29 min) than in CT/MRI-negative patients (median PTA duration, < 1 min). There was no significant difference in GCS or LOC between CT/MRI-negative and -positive mTBI groups at $p < 0.05$ (Table 1).

Conventional CT and MRI results

Table 2 shows that MRI identifies many more acute traumatic intracranial lesions than CT. TBI-CDE–defined pathoanatomic features observed on head CT upon ED presentation and early brain MRI in our study population consisted of the following: nondepressed skull fracture; EDH; SDH; SAH; brain contusion; and hemorrhagic axonal injury. Hemorrhagic axonal injury was observed on many brain MRI exams, but on only one head CT, in this study. Other TBI-CDE features, such as midline shift ≥ 5 mm and partial or complete basal cistern effacement that are more characteristic of moderate-to-severe TBI, were also not observed on any head CT or brain MRI in this study. In addition, no depressed skull fracture was observed in this study. As shown in Table 2, all 4 of 4 (100%) patients with CT evidence of contusion also had MRI evidence of contusion ± hemorrhagic axonal injury. In contrast, 7 of 11 (64%) patients with MRI evidence of contusion and 25 of 27 (93%) with MRI evidence of hemorrhagic axonal injury had no CT evidence of any parenchymal injury. Three patients with nondepressed skull fractures had no CT or conventional MRI traumatic intracranial abnormality and were classified as CT/MRI-negative mTBI (analogous to the classification of patients with isolated nondepressed skull fracture and no acute intracranial hemorrhage as "uncomplicated" mTBI in previous literature[38]).

Whole-brain voxel-wise nonparametric statistical comparison of diffusion tensor imaging measures in mTBI (n = 76) versus control subjects (n = 50)

Figure 1A shows many statistically significant areas of reduced FA in the 76 mTBI patients, compared to the 50 control subjects, using TBSS and voxel-wise nonparametric statistical comparison implemented in the FSL randomise algorithm and corrected for multiple comparisons with TFCE. mTBI patients demonstrated significantly lower FA in the right internal and external capsules,

TABLE 2. CT AND CONVENTIONAL MRI FINDINGS IN 76 mTBI PATIENTS

	CT				
	Normal	Nondepressed skull fracture only	Acute extraaxial hemorrhage (EDH, SDH, SAH) with no parenchymal injury	Contusion ± extraaxial hemorrhage	Hemorrhagic axonal injury only
MRI					
No parenchymal injury	41	3	2	0	0
Hemorrhagic axonal injury only	17	0	1	0	1
Contusion only	0	0	0	3	0
Both hemorrhagic axonal injury and contusion	1	1	5	1	0

Gray shaded boxes comprise uncomplicated mTBI (no CT evidence of acute intracranial hemorrhage or depressed skull fracture).[38]

CT, computed tomography; MRI, magnetic resonance imaging; mTBI, mild traumatic brain injury; EDH, epidural hematoma; SDH, subdural hematoma; SAH, subarachnoid hemorrhage.
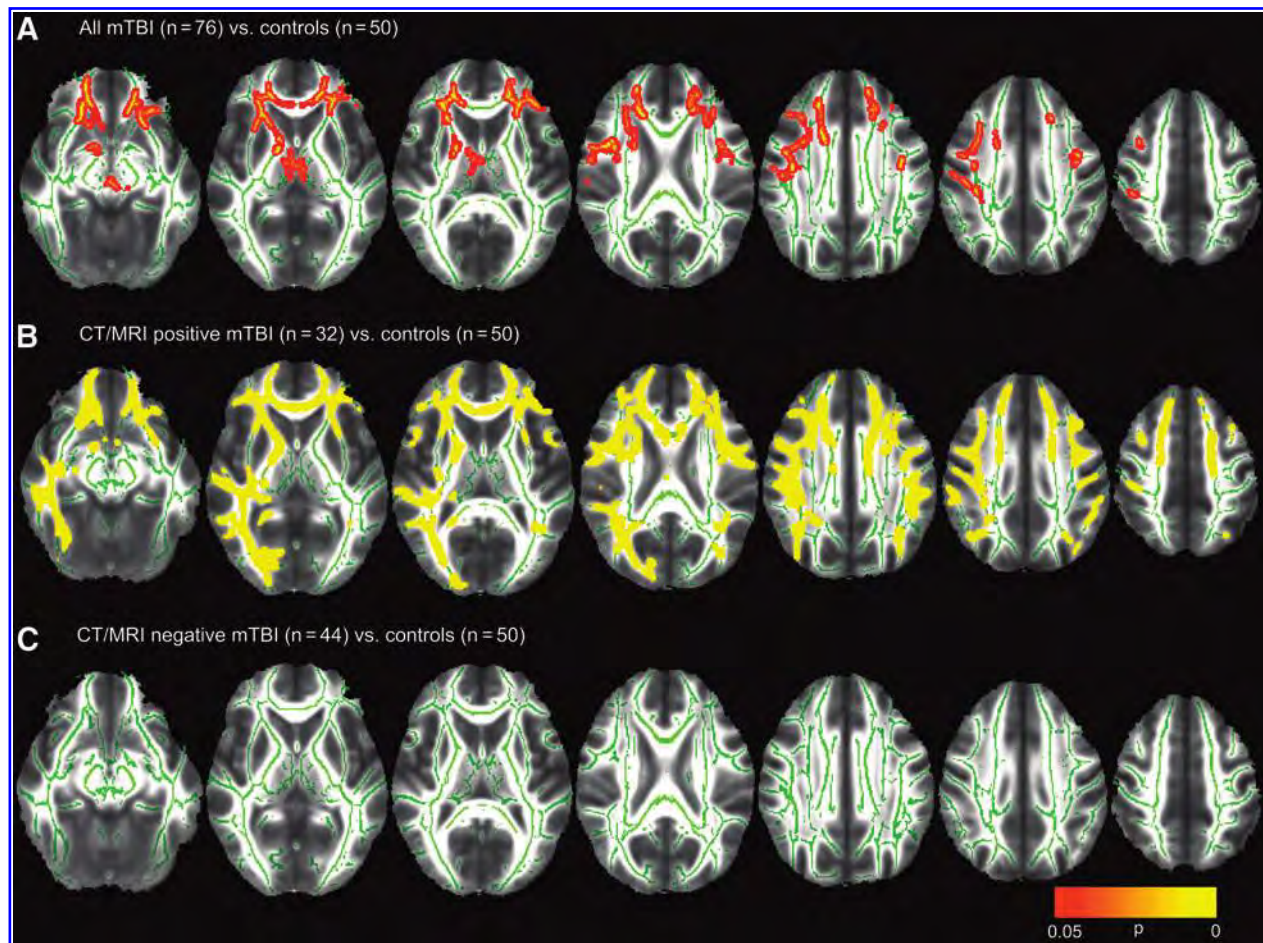
FIG. 1. Voxel-wise nonparametric statistical comparison between mild traumatic brain injury (mTBI) patients and controls, with corrections for multiple voxel-wise comparisons using threshold-free cluster enhancement. This analysis was used to compare (**A**) 76 mTBI patients to 50 controls, (**B**) the subgroup of 32 computed tomography/magnetic resonance imaging (CT/MRI)-positive mTBI patients to the 50 controls, and (**C**) the subgroup of 44 CT/MRI-negative patients to the 50 controls. Voxel clusters with statistically significant differences in fractional anisotropy (FA) between mTBI and control groups at $p < 0.05$ are shown in red/orange/yellow, with yellow denoting greater statistical significance. (A) shows that the 76 mTBI patients demonstrated significantly lower FA in the genu of the corpus callosum, uncinate fasciculi, and anterior corona radiata bilaterally as well as right internal and external capsules, compared to the 50 control subjects. (B) In a comparison of a much smaller subgroup of 32 CT/MRI-positive mTBI patients to the 50 controls, areas of reduced FA were even more extensive and attained much higher levels of statistical significance (yellow regions, corresponding to $p < 0.01$) than in the comparison of 76 mTBI patients to the control group (mostly red/orange areas, corresponding to $p < 0.05$, in [A]). (C) shows that this method demonstrated no evidence for white matter injury in 44 CT/MRI-negative mTBI patients, compared to the 50 controls. Color image is available online at www.liebertpub.com/neu

genu of the corpus callosum, and uncinate fasciculi and anterior corona radiata bilaterally.

No voxel with significantly increased FA, and no significant group differences in MD, RD or AD, were found in mTBI patients, compared to the control group at $p < 0.05$ using TBSS, randomise, and correction for multiple comparisons with TFCE.

Whole-brain voxel-wise nonparametric statistical comparison of diffusion tensor imaging measures in CT/MRI-positive mTBI (n = 32) versus control subjects (n = 50)

Figure 1B shows many highly statistically significant areas of reduced FA in the CT/MRI-positive subgroup of mTBI patients, compared to the control group. Despite the expected loss of statistical power for this comparison of a much smaller subgroup of 32 CT/MRI-positive mTBI patients to the control group, areas of

reduced FA were even more extensive and attained higher levels of statistical significance (yellow regions, corresponding to $p < 0.01$; Fig. 1B) than in the comparison of 76 mTBI patients to the control group (mostly red/orange areas, corresponding to $p < 0.05$; Fig. 1A). mTBI patients demonstrated significantly lower FA in the genu and body of the corpus callosum, the external capsules, uncinate fasciculi, and anterior corona radiata bilaterally, the right internal capsule, and the right inferior longitudinal and inferior fronto-occipital fasciculi. Extensive areas of increased RD were also observed in the 32 CT/MRI-positive mTBI patients, relative to the control group, whereas none had been observed in the comparison of 76 mTBI patients to the control group. No voxel with increased FA or reduced RD was observed in CT/MRI-positive mTBI patients, relative to controls, at $p < 0.05$. There were also no voxels in which MD or AD differed significantly between CT/MRI-positive mTBI and control groups at $p < 0.05$.

No significant group differences in FA (Fig. 1C), MD, RD, or AD were found between CT/MRI-negative mTBI and control groups at $p < 0.05$.

Whole-brain voxel-wise nonparametric statistical comparison of diffusion tensor imaging measures in most highly educated versus least educated control subjects (n = 50)

To exclude the possibility that the nonsignificant differences in educational level among CT/MRI-positive mTBI, CT/MRI-negative mTBI, and control groups (Table 1) could result in group differences in DTI parameters that could be erroneously attributed to mTBI, we assessed for group differences in DTI parameters between control subjects with the longest and shortest duration of education. The 50 control subjects were divided into two groups, one consisting of 25 patients with the most years of formal education and the other consisting of 25 patients with the fewest years of formal education. There were no statistically significant group differences in DTI parameters between these groups at $p < 0.05$. This analysis was performed to exclude the possibility that the statistically significant group differences in FA shown in Figure 1A and 1B were attributable mostly to educational level or to other socioeconomic factors that might be correlated with educational level.

Region-of-interest analysis of individual mTBI subjects

Table 3 shows that abnormally low FA (FA more than 2.2 SDs below the control-group mean) was observed in ≥ 1 ROIs for 14 of 32 CT/MRI-positive mTBI (43.8%), 11 of 44 CT/MRI-negative mTBI (25.0%), and 5 of 50 (10.0%) control subjects. Pearson's χ^2 test showed a highly significant difference between the pro-

portions of CT/MRI-positive mTBI patients (43.8%) and control subjects (10.0%) with ≥ 1 abnormal ROIs ($p = 0.0006$). There was a trend toward a significant difference between the proportions of CT/MRI-negative mTBI patients (25.0%) and controls (10.0%) with ≥ 1 abnormal ROIs ($p = 0.06$). Finally, there was no significant difference between the proportions of CT/MRI-positive mTBI patients (43.8%) and CT/MRI-negative mTBI patients (25.0%) with ≥ 1 abnormal ROIs ($p = 0.14$).

Table 3 also shows that there was no significant difference ($p = 0.93$) among the proportions of CT/MRI-positive, CT/MRI-negative, and control subjects with ≥ 1 ROI with abnormally high FA (FA more than 2.2 SDs above the control-group mean).

Outcome measures

Table 4 summarizes 3- and 6-month outcome measures of participants. There were no statistically significant differences in any 3- or 6-month outcome measure between CT/MRI-negative and -positive mTBI groups at $p < 0.05$. For the TMT A and B, the actual times for test completion, the corresponding TMT A and B z-scores adjusted for age,[52] as well as the proportion of abnormal performances worse than 2 SDs from the age-adjusted mean, were compared between CT/MRI-positive and -negative mTBI groups, and none showed a statistically significant difference at $p < 0.05$.

Spearman's correlation

Table 5 shows the pair-wise Spearman's correlation coefficients between 3- and 6-month outcome measures and demographic, socioeconomic, clinical, CT, and MRI predictors. Gender, employment status, GCS at ED arrival, PTA, PTA duration, LOC, and history of previous TBI with LOC up to 5 min were not significantly correlated with any outcome variable, and these predictors were thus omitted from Table 5, for brevity. Similarly, worse outcomes, as measured by the 6-month TMT A (both age-adjusted z-score and the dichotomized score), TMT B (z-score), CVLT-II (both age-adjusted scaled score and dichotomized score), and WAIS-IV PSI

TABLE 3. DTI REGION-OF-INTEREST (ROI) ANALYSIS: GROUP DIFFERENCES IN PRESENCE OF ONE OR MORE ABNORMAL ROIS AMONG CT/MRI-NEGATIVE MTBI, CT/MRI-POSITIVE MTBI, AND CONTROL SUBJECTS

	CT/MRI-negative mTBI (no acute traumatic intracranial abnormality or depressed skull fracture on CT or conventional MRI) (44 subjects)	CT/MRI-positive mTBI (positive acute traumatic intracranial abnormality and/or depressed skull fracture on CT and/or conventional MRI) (32 subjects)	Controls (50 subjects)
	Number of subjects (proportion of subjects)	*Number of subjects (proportion of subjects)*	*Number of subjects (proportion of subjects)*
One or more ROIs with FA more than 2.2 SDs below control-group mean	11 (25.0%)[a,b]	14 (43.8%)[b]	5 (10.0%)[a]
One or more ROIs with FA more than 2.2 SDs above control group mean	8 (18.2%)[c]	5 (15.6%)[c]	8 (16.0%)[c]

[a,b,c]Each superscript denotes a subset of participants whose column proportions do not differ significantly from one another, by Pearson's χ^2 test with $p < 0.05$. **Row 1:** There was a statistically significant difference between CT/MRI-positive mTBI (43.8%) and control subjects (10.0%), with one or more ROIs with FA more than 2.2 SDs *below* the control group mean ($p = 0.0006$). There was no significant difference between CT/MRI-negative mTBI patients (25.0%) and controls (10.0%; $p = 0.06$). There was also no significant difference between CT/MRI-positive (43.8%) and CT/MRI-negative mTBI patients (25.0%; $p = 0.14$). **Row 2:** There was no significant difference among the proportions of CT/MRI-negative mTBI (18.2%), CT/MRI-positive mTBI (15.6%), and control subjects (16.0%) with one or more ROIs with FA more than 2.2 SDs *above* the control group mean ($p = 0.96$).

DTI, diffusion tensor imaging; ROI, region of interest; CT, computed tomography; MRI, magnetic resonance imaging; mTBI, mild traumatic brain injury; FA, fractional anisotropy; SD, standard deviation.

TABLE 4. GROUP DIFFERENCES IN 3- AND 6-MONTH OUTCOME MEASURES BETWEEN 32 CT/MRI-POSITIVE mTBI
AND 44 CT/MRI-NEGATIVE mTBI PATIENTS

	CT/MRI-negative (no acute traumatic intracranial abnormality or depressed skull fracture on CT or conventional MRI) (44 subjects)		CT/MRI-positive (acute traumatic intracranial abnormality or depressed skull fracture on CT and/or conventional MRI) (32 subjects)		Analysis for group differences between CT/MRI negative, CT/MRI positive	
3-month outcome measure	*Score*	*Number of patients*	*Score*	*Number of patients*		
3-month GOS-E[a]	4	1	4	0	U=485; Z=−1.4; p=0.17	Mann-Whitney U test
	5	6	5	3		
	6	3	6	10		
	7	13	7	8		
	8	18	8	8		
6-month outcome measures						
6-month GOS-E[b]	4	1	4	0	U=459; z=−0.67; p=0.52	Mann-Whitney U test
	5	4	5	3		
	6	7	6	7		
	7	13	7	9		
	8	14	8	7		
RPQ-3[b] Median (25%, 75%)	2.0 [0.0,4.0]		1.5 [0.0,4.3]		U=467; z=−0.55; p=0.59	Mann-Whitney U test
RPQ-13[b] Median (25%, 75%)	7.0 [4.0,16.0]		14.0 [3.3,21.0]		U=441; z=−0.89; p=0.38	
CVLT-II scaled score[c]	54±11		57±9		t(55)=0.91; p=0.37	Two-tailed t-test
WAIS IV PSI[d] percentile	58%±28%		62%±27%		t(57)=0.45; p=0.65	
TMT A[e]						
• Time (sec)	31±13		30±9		t(59)=−0.37; p=0.71	Two-tailed t-test
• Time (z-score)	0.68±1.45		0.50±1.29		t(59)=−0.51; p=0.62	
• TMT A >2 SDs above mean	Yes No	7 28	Yes No	3 23	U=417; z=−0.88; p=0.38	Mann-Whitney U test
TMT B[e]						
• Time (sec)	65±27		69±27		t(59)=0.51; p=0.61	Two-tailed t-test
• Time (z-score)	0.93±1.75		1.09±1.94		t(59)=0.34; p=0.74	
• TMT B >2 SDs above mean	Yes No	8 27	Yes No	8 18	U=419; z=−0.69; p=0.56	Mann-Whitney U test

[a]Three CT/MRI-negative mTBI and 3 CT/MRI-positive mTBI patients did not complete 3-month GOS-E evaluation.
[b]Five CT/MRI-negative mTBI and 6 CT/MRI-positive mTBI patients did not complete 6-month GOS-E, RPQ-3, or RPQ-13.
[c]Eleven CT/MRI-negative mTBI and 8 CT/MRI-positive mTBI patients did not complete 6-month CVLT-II.
[d]Ten CT/MRI-negative mTBI and 7 CT/MRI-positive mTBI patients did not complete 6-month WAIS IV.
[e]Nine CT/MRI-negative mTBI and 6 CT/MRI-positive mTBI patients did not complete 6-month TMT A or TMT B.

CT, computed tomography; MRI, magnetic resonance imaging; mTBI, mild traumatic brain injury; GOS-E, Glasgow Outcome Scale – Extended; CVLT-II, California Verbal Learning Test–Second edition; RPQ, Rivermead Postconcussion Symptoms Questionnaire; TMT, Trail Making Test; SD, standard deviation; WAIS IV PSI, Wechsler Adult Intelligence Scale–Fourth edition, Processing Speed Index.

TABLE 5. SPEARMAN'S CORRELATION COEFFICIENTS (ρ) BETWEEN OUTCOME MEASURES[a] AND DEMOGRAPHIC, SOCIOECONOMIC, CLINICAL, AND IMAGING PREDICTORS[b] IN 76 mTBI PATIENTS

	Demographic, clinical, socioeconomic				Day-of-injury head CT					Early brain MRI (11.2±3.3 days postinjury)		
	Age	Education (years)	Neuropsychiatric history	History of alcohol or drug problem	Nondepressed calvarial or skull base fracture	EDH	SDH	SAH	Any CT contusion	Any MRI contusion	Any MRI T2* evidence of hemorrhagic axonal injury[b]	Any DTI axonal injury (≥1 ROI with FA > 2.2 SDs below control-group mean)
3-month GOS-E (N=70)	-0.30* p=0.013	0.27* p=0.02	-0.27* p=0.03 (18 pos.)	-0.12 p=0.34 (34 pos.)	-0.12 p=0.33 (12 pos.)	-0.08 p=0.54 (3 pos.)	-0.23 p=0.06 (9 pos.)	-0.28* p=0.02 (6 pos.)	-0.22 p=0.07 (5 pos.)	-0.36† p=0.003 (11 pos.)	-0.12 p=0.34 (24 pos.)	-0.34† p=0.004 (23 pos.)
6-month GOS-E (N=65)	-0.18 p=0.16	0.31* p=0.011	-0.30* p=0.02 (17 pos.)	-0.18 p=0.15 (31 pos.)	-0.13 p=0.32 (10 pos.)	0.01 p=0.97 (2 pos.)	-0.17 p=0.18 (7 pos.)	-0.20 p=0.11 (5 pos.)	-0.19 p=0.14 (4 pos.)	-0.19 p=0.12 (9 pos.)	-0.03 p=0.84 (22 pos.)	-0.25* p=0.04 (20 pos.)
Abnormal TMT B (>2 SDs above age-adjusted mean) at 6 months (N=61)	0.11 p=0.42	-0.18 p=0.17	-0.02 p=0.90 (16 pos.)	0.01 p=0.94 (30 pos.)	-0.14 p=0.27 (9 pos.)	-0.11 p=0.40 (2 pos.)	0.02 p=0.88 (7 pos.)	0.09 p=0.47 (5 pos.)	-0.16 p=0.22 (4 pos.)	0.07 p=0.61 (9 pos.)	0.17 p=0.18 (22 pos.)	0.32* p=0.011 (19 pos.)
6-month RPQ-3 (N=65)	0.23 p=0.07	-0.23 p=0.06	0.36† p=0.003 (17 pos.)	0.25* p=0.045 (31 pos.)	-0.12 p=0.32 (10 pos.)	-0.21 p=0.09 (2 pos.)	0.11 p=0.37 (7 pos.)	0.01 p=0.93 (5 pos.)	0.07 p=0.56 (4 pos.)	0.03 p=0.84 (9 pos.)	-0.10 p=0.45 (22 pos.)	0.18 p=0.14 (20 pos.)
6-month RPQ-13 (N=65)	0.26* p=0.04	-0.28* p=0.02	0.31* p=0.013 (17 pos.)	0.16 p=0.20 (31 pos.)	0.02 p=0.85 (10 pos.)	-0.07 p=0.60 (2 pos.)	0.19 p=0.14 (7 pos.)	0.16 p=0.21 (5 pos.)	0.21 p=0.10 (4 pos.)	0.12 p=0.34 (9 pos.)	0.02 p=0.85 (22 pos.)	0.29* p=0.02 (20 pos.)

[a]No statistically significant correlation was found between any imaging, demographic, socioeconomic, or clinical predictor and worse performance on 6-month TMT A (either z-score or dichotomized score), TMT B (z-score), CVLT-II (scaled score or dichotomized score), or WAIS-IV PSI (scaled score or dichotomized score), except for correlation of CVLT-II scaled score with years of education ($\rho=0.27$; $p=0.04$) and correlation of age with TMT A z- score ($\rho=-0.33$; $p=0.0097$). Thus, for brevity, these outcome measures are omitted from Table 5.

[b]No statistically significant correlation was found between gender, unemployment, GCS at emergency department arrival, PTA, PTA duration, LOC, or history of previous TBI (with LOC not exceeding 5 min) and any outcome variable. Thus, for brevity, these predictors are omitted from Table 5. There was a trend toward significant correlation between 6-month GOS-E and unemployed status ($\rho=-0.24$; $p=0.056$).

*$p<0.05$ (light-gray boxes); †$p<0.01$ (dark-gray boxes).

CT, computed tomography; MRI, magnetic resonance imaging; EDH,epidural hematoma; SDH, subdural hematoma; SAH, subarachnoid hemorrhage; DTI, diffusion tensor imaging; ROI, region of interest; SD, standard deviation; FA, fractional anisotropy; GOS-E, Glasgow Outcome Scale-Extended; TMT, Trail Making Test; RPQ, Rivermead Postconcussion Questionnaire; CVLT, California Verbal Learning Test; WAIS, Wechsler Adult Intelligence Scale; pos., positive.

Table 6a. Multivariable Ordinal Logistic Regression of 3- and 6-Month GOS-E Versus Statistically Significant Clinical, Demographic, Socioeconomic, CT, and MRI Predictors From Table 5

Outcome variable	Predictor	Predictor values	Univariable odds ratio per unit decrease in GOS-E (95% CI), p value	Multivariable odds ratio of predictor per unit decrease in GOS-E (95% CI), p value	Multivariable model significance	Cox and Snell pseudo-R^2	Nagelkerke pseudo-R^2
3-month GOS-E (N=70)	Age	32.4±10.8 years	1.07 per year (1.03, 1.1); p=0.002[†]	1.07 per year (1.03, 1.1); p=0.002[†]	p=0.00002[§]	34.5%[§]	36.9%[§]
	Education	14.5±2.5 years	0.79 per year (0.66, 0.94); p=0.0101*	0.79 per year (0.65, 0.96); p=0.02*			
	Neuropsychiatric history	Yes (18) No (52)	3.3 (1.2, 8.8); p=0.02*	1.9 (0.65, 5.3); p=0.25			
	CT subarachnoid hemorrhage	Yes (6) No (64)	p=0.053	Excluded because of collinearity (see text)			
	MRI contusion present	Yes (11) No (59)	4.9 (1.5, 16.4); p=0.0098[†]	3.1 (0.87, 11.0); p=0.08			
	DTI axonal injury (≥1 ROI with FA>2.2 SD below control-group mean)	Yes (23) No (47)	3.9 (1.5, 10.0); p=0.005[†]	2.6 (0.94, 7.0); p=0.07			
6-month GOS-E (N=65)	Education	14.8±2.5 years	0.82 (0.68, 0.98); p=0.03*	0.90 per year (0.74, 1.08); p=0.26	p=0.013*	15.3%*	16.3%*
	Neuropsychiatric history	Yes (17) No (48)	3.7 (1.3, 10.5); p=0.014*	2.7 (0.92, 7.9); p=0.07			
	Any DTI axonal injury (≥1 ROI with FA>2.2 SD below control-group mean)	Yes (20) No (45)	2.7 (1.01, 7.1); p=0.048*	2.5 (0.83, 6.1); p=0.11			

TABLE 6B. MULTIVARIABLE LINEAR REGRESSION OF 6-MONTH RPQ-13 VERSUS STATISTICALLY SIGNIFICANT CLINICAL, DEMOGRAPHIC, SOCIOECONOMIC, CT, AND MRI PREDICTORS FROM TABLE 5

Outcome variable	Predictor	Predictor values	Univariable standardized coefficient β; p value	Multivariable standardized coefficient β; p value	F (degrees of freedom)	Overall model significance	Adjusted R^2
6-month RPQ-13 ($N=65$)	Age	32.0 ± 10.8 years	0.32; $p=0.009$[†]	0.26; $p=0.02$*	$F_{(4,60)}=6.0$[‡]	$p=0.0004$[‡]	23.7%[‡]
	Education	14.8 ± 2.5 years	−0.29; $p=0.02$*	−0.20; $p=0.10$			
	Neuropsychiatric history	Yes (17) No (48)	0.36; $p=0.003$[†]	0.22; $p=0.07$			
	Any DTI axonal injury (≥1 ROI with FA>2.2 SDs below control-group mean)	Yes (20) No (45)	0.31; $p=0.012$*	0.21; $p=0.07$			

TABLE 6C. UNIVARIABLE BINARY LOGISTIC REGRESSION OF 6-MONTH TMT B VERSUS STATISTICALLY SIGNIFICANT CLINICAL, DEMOGRAPHIC, SOCIOECONOMIC, CT, AND MRI PREDICTORS FROM TABLE 5

Outcome variable	Predictor	Predictor values	Univariable odds ratio (95% CI), p value	Multivariable odds ratio (95% CI), p value	Multivariable model significance	Cox and Snell pseudo-R^2	Nagelkerke pseudo-R^2
6-month TMT B >2 SDs above age-adjusted mean ($N=61$)	Any DTI axonal injury (≥1 ROI with FA>2.2 SDs below control-group mean)	Yes (19) No (42)	4.5 (1.3, 15.1); $p=0.014$*	4.5 (1.3, 15.1); $p=0.014$*	$p=0.015$*	9.5%*	13.9%*

CT, computed tomography; MRI, magnetic resonance imaging; GOS-E,Glasgow Outcome Scale-Extended; CI, confidence interval; DTI, diffusion tensor imaging; ROI, region of interest; FA, fractional anisotropy; SD, standard deviation; RPQ, Rivermead Postconcussion Questionnaire; TMT B, Trail Making Test B.
*$p \leq 0.05$ (light-gray box) [†]$p \leq 0.01$ (medium-gray box) [‡]$p \leq 0.001$ (dark-gray box) [§]$p \leq 0.0001$ (dark-gray box).

(both age-adjusted scaled score and dichotomized score), were not significantly correlated with any imaging, clinical, demographic, or socioeconomic predictor (with the exception of modest correlations between CVLT-II scaled score and years of education and between age and TMT A z-score), and these outcome measures were thus also omitted from Table 5, for brevity.

Table 5 shows that among demographic, clinical, and socioeconomic predictors, previous history of neuropsychiatric disorder was the most consistent predictor of outcome, demonstrating statistically significant correlations with 3-month GOS-E ($\rho = -0.27$; $p = 0.03$), 6-month GOS-E ($\rho = -0.30$; $p = 0.02$), 6-month RPQ-3 ($\rho = 0.36$; $p = 0.003$), and 6-month RPQ-13 ($\rho = 0.31$; $p = 0.013$).

Among the imaging predictors, DTI evidence of one or more ROIs with abnormally reduced FA (> 2.2 SDs below control-group mean) was the most consistent predictor of outcome, demonstrating statistically significant correlations with 3-month GOS-E ($\rho = -0.34$; $p = 0.004$), 6-month GOS-E ($\rho = -0.25$; $p = 0.04$), abnormal 6-month TMT B ($\rho = 0.32$; $p = 0.011$), and 6-month RPQ-13 ($\rho = 0.29$; $p = 0.02$). Among other imaging predictors, MRI evidence of contusion was significantly correlated with 3-month GOS-E ($\rho = -0.36$; $p = 0.003$), as was CT evidence of SAH, though more weakly ($\rho = -0.28$; $p = 0.02$).

Regression of 3- and 6-month outcome measures on demographic, clinical, and imaging predictors

Based on the results of Spearman's correlation analysis (Table 5), we constructed regression models of each of five outcome measures: 3-month GOS-E; 6-month GOS-E; 6-month TMT B (dichotomized score); 6-month RPQ-3; and 6-month RPQ-13. The predictive (independent) variables in the model for each outcome measure were limited to only those predictors that had demonstrated a statistically significant Spearman's correlation with that outcome measure in Table 5. This resulted in a multivariable regression model for four outcome measures (3- and 6-month GOS-E, 6-month RPQ-3, and 6-month RPQ-13) and a univariable regression model for one outcome measure (6-month TMT B dichotomized score). No regression model was constructed for any outcome measure that lacked a statistically significant Spearman's correlation with at least one predictor.

For the 3-month GOS-E, age, number of years of education, neuropsychiatric history, MRI evidence for contusion, and DTI evidence of one or more abnormal ROIs with FA more than 2.2 SDs below the control-group mean demonstrated statistically significant univariable odds ratios (ORs; Table 6A), compatible with the Spearman's correlation results from Table 5. The multivariable model for 3-month GOS-E, including all of these predictors, was also significant (pseudo-R^2 of 34.5–36.9%; $p = 0.00002$; Table 6A). Although CT evidence of SAH demonstrated a nearly statistically significant univariable OR ($p = 0.053$), it was excluded from the multivariable model because of collinearity with MRI evidence of contusion. In particular, unstable ORs and a variance inflation factor > 2 were observed for CT evidence of SAH and MRI evidence of contusion when both were simultaneously included in the multivariable model.

For the 6-month GOS-E, years of education, neuropsychiatric history, and DTI evidence of one or more abnormal ROIs with FA more than 2.2 SDs below the control-group mean demonstrated statistically significant univariable ORs (Table 6A), compatible with Spearman's correlation results from Table 5. The multivariable model for 6-month GOS-E, including all of these predictors, was also significant (pseudo-R^2 of 15.3–16.3%; $p = 0.013$; Table 6A).

For 6-month RPQ-13, age, years of education, neuropsychiatric history, and DTI evidence of one or more abnormal ROIs with FA more than 2.2 SDs below the control group mean demonstrated statistically significant univariable ORs, consistent with Spearman's correlation results from Table 5. The multivariable linear regression model for 6-month RPQ-13, including all of these predictors was also significant (adjusted R^2 of 23.7%; $p = 0.0004$; Table 6B).

Because the 6-month TMT B was significantly correlated with only one predictor (Table 5), a univariable binary logistic regression model was constructed for this outcome measure. DTI evidence of one or more ROIs with abnormally reduced FA demonstrated a statistically significant univariable OR of 4.5 ($p = 0.014$; Table 6C).

For 6-month RPQ-3, only neuropsychiatric history and history of drug or alcohol abuse demonstrated statistically significant univariable ORs. The multivariable ordinal logistic regression model for 6-month RPQ-3, including both of these predictors, was also statistically significant (pseudo-R^2 of 9.5–13.9%; $p = 0.015$).

Analysis of subset of patients without pre-existing neuropsychiatric or substance abuse history

Most previous studies of DTI in mTBI have excluded patients with history of neuropsychiatric disease or substance abuse on the grounds that DTI results could be influenced by one or both of these factors. We performed whole-brain voxel-wise nonparametric statistical comparison of FA in CT/MRI-negative patients with a positive history of neuropsychiatric disease or substance abuse ($n = 24$), compared to those without ($n = 20$). Many areas of reduced FA at $p < 0.25$ (though not at $p < 0.05$) were found. Therefore, to address the possibility that a previous history of substance abuse and/or neuropsychiatric disease could have influenced our results, we separately analyzed the subset of mTBI patients without such history. Supplementary Tables S2 and S3 (see online supplementary material at http://www.liebertpub.com) summarize demographic, socioeconomic, and clinical characteristics, and 3- and 6-month outcome measures, for this subset of 37 mTBI patients without history of substance abuse or neuropsychiatric disease.

Figure 2A is analogous to Figure 1A, but compares only mTBI patients without history of neuropsychiatric disorder or substance abuse ($n = 37$) to control subjects ($n = 50$). Unlike Figure 1A, no significant group differences in FA (Fig. 2A), MD, RD, or AD were found.

Analogous to Figure 1B, Figure 2B compares CT/MRI-positive mTBI patients without neuropsychiatric or substance abuse history ($n = 17$) to controls ($n = 50$). There are extensive areas of reduced FA in the CT/MRI-positive mTBI patients, despite the expected loss of statistical power for comparison of this small subgroup of only 17 CT/MRI-positive mTBI patients to controls. No region of increased FA, or of increased or reduced MD, AD, or RD, was observed in CT/MRI-positive mTBI patients, relative to controls, at $p < 0.05$.

Finally, analogous to results in Figure 1C, no significant group differences in FA (Fig. 2C), MD, RD, or AD were found in CT/MRI-negative patients without neuropsychiatric or substance abuse history ($n = 20$), compared to controls ($n = 50$), at $p < 0.05$.

Table 7 shows that all 17 of 17 (100.0%) CT/MRI-positive mTBI patients without neuropsychiatric or substance abuse history had abnormal conventional MRI, but only 5 of 17 (24%) had abnormal head CT. One patient with a nondepressed anterior skull base fracture had no CT or MRI evidence of traumatic brain lesion or intracranial hemorrhage and was classified as CT/MRI-negative mTBI (analogous to the classification of isolated nondepressed skull fracture as uncomplicated mTBI in previous literature[38]). On conventional MRI
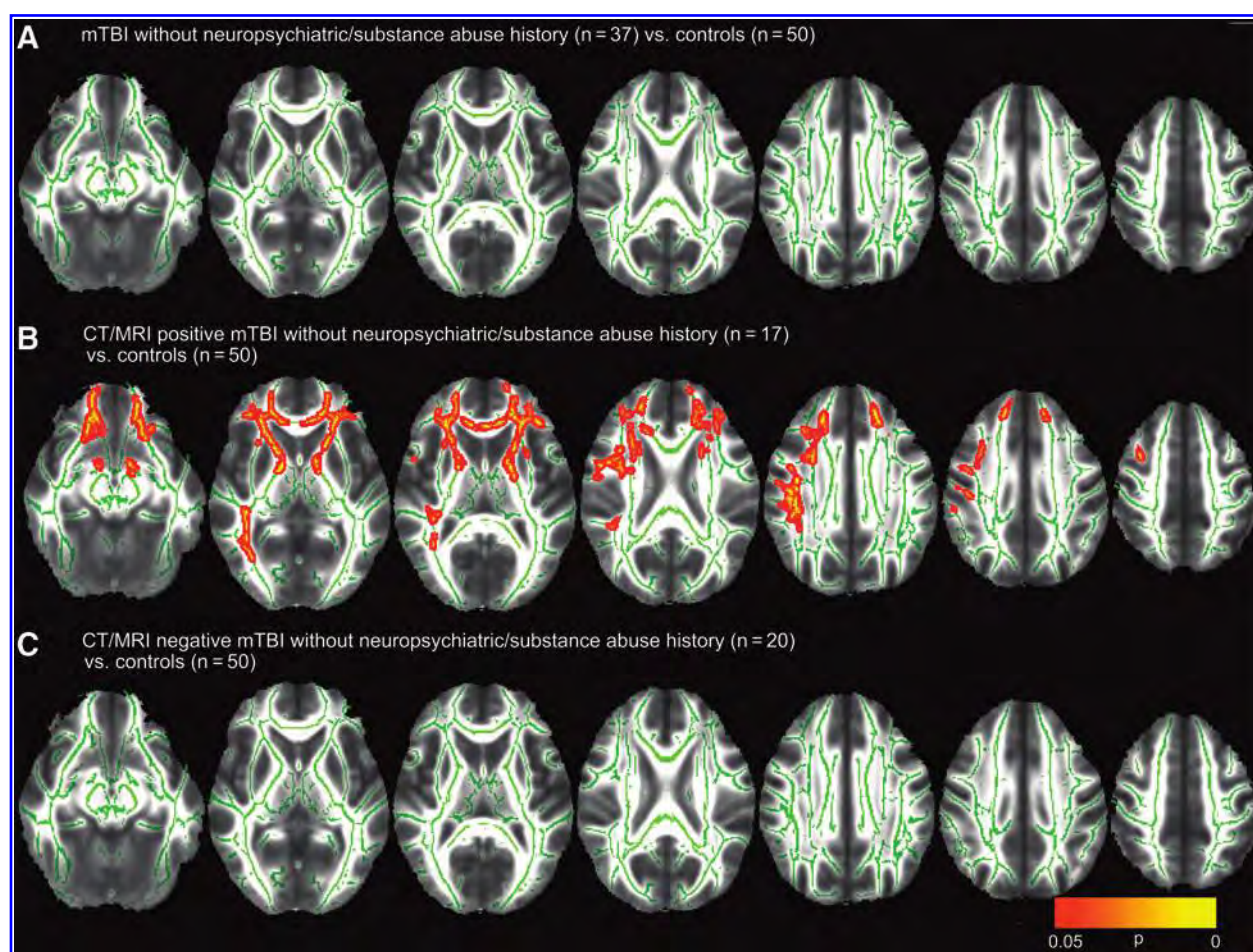
FIG. 2. Voxel-wise nonparametric statistical comparison between mild traumatic brain injury (mTBI) patients without previous history of substance abuse or other neuropsychiatric disorder and controls, with corrections for multiple voxel-wise comparisons using threshold-free cluster enhancement. This analysis was used to compare (**A**) 37 mTBI patients without pre-existing substance abuse or neuropsychiatric history to 50 controls, (**B**) the subgroup of 17 computed tomography/magnetic resonance imaging (CT/MRI)-positive mTBI patients to the 50 controls, and (**C**) the subgroup of 20 CT/MRI-negative patients to the 50 controls. Voxel clusters with statistically significant differences in fractional anisotropy (FA) between mTBI and control groups at $p < 0.05$ are shown in red/orange/yellow, with yellow denoting greater statistical significance. (B) shows that CT/MRI-positive mTBI patients without substance abuse or neuropsychiatric history demonstrated significantly lower FA in the anterior and posterior limbs of the internal capsules, external capsules, uncinate fasciculi, genu of the corpus callosum, and anterior corona radiata bilaterally. In contrast, (C) shows that this method demonstrated no evidence for white matter injury in CT/MRI-negative mTBI. Color image is available online at www.liebertpub.com/neu

sequences, most CT/MRI-positive mTBI patients (11 of 17; 64.7%) demonstrated isolated foci of hemorrhagic axonal injury without brain contusion; 4 of 17 (23.5%) demonstrated both hemorrhagic axonal injury and brain contusion; 1 of 17 (5.9%) demonstrated brain contusions and EDH; and 1 of 17 (5.9%) had isolated SDH.

Tables 7 and 8 also show results of ROI analysis of the 17 CT/MRI-positive and 20 CT/MRI-negative mTBI patients without a history of neuropsychiatric or substance abuse. Table 7 shows lesions with abnormally low FA (FA more than 2.2 SDs below the control-group mean) in individual patients. Table 8 shows that such lesions were observed in ≥ 1 ROIs for 9 of 17 CT/MRI-positive mTBI (52.9%), 2 of 20 CT/MRI-negative mTBI (10.0%), and 5 of 50 (10.0%) control subjects. Fisher's exact test showed a highly significant difference between the proportions of CT/MRI-positive mTBI patients (52.9%) and control subjects (10.0%) with ≥ 1 abnormal ROIs ($p = 0.0006$). There was also a highly significant difference between the proportions of CT/MRI-positive mTBI patients (52.9%) and CT/MRI-negative mTBI patients (10.0%)

with ≥ 1 abnormal ROIs ($p = 0.0097$). However, there was no difference in the proportions of CT/MRI-negative mTBI patients (10.0%) and controls (10.0%) with ≥ 1 abnormal ROIs ($p = 1.0$). Finally, there was no significant difference among CT/MRI-positive mTBI, CT/MRI-negative mTBI, and control subject groups in terms of the proportion of subjects with ≥ 1 ROI with abnormally high FA ($p = 0.75$).

Table 9 is analogous to Table 5 and shows the pairwise Spearman's correlations between 3- and 6-month outcome measures and demographic, socioeconomic, clinical, CT, and MRI predictors in patients without a history of neuropsychiatric or substance abuse. Except for an expected correlation[52] of years of education with TMT B z-score ($\rho = -0.50$; $p = 0.007$), and correlation of TMT A z-score with age ($\rho = -0.39$; $p = 0.04$) and with PTA duration ($\rho = 0.48$; $p = 0.014$), no demographic, socioeconomic, or clinical variable (age, gender, employment status, GCS, PTA, PTA duration, LOC, or history of earlier TBI) was otherwise significantly correlated at $p < 0.05$ with worse performance on any outcome measure; all demographic,

TABLE 7. CT, CONVENTIONAL MRI AND DTI FINDINGS IN CT/MRI-POSITIVE AND CT/MRI-NEGATIVE mTBI PATIENTS WITHOUT PRE-EXISTING SUBSTANCE ABUSE OR NEUROPSYCHIATRIC HISTORY

Patient	ACR Left	ACR Right	ALIC Left	ALIC Right	EC Left	EC Right	SLF Left	SLF Right	SS Left	SS Right	CGH Left	CGH Right	CT findings	Conventional MRI findings
CT/MRI-positive mTBI														
1	x			x									Normal	2 microhemorrhages (R posterior limb of internal capsule)
2					x								Normal	1 microhemorrhage (posterior L temp WM)
3						x					x		Normal	1.3 cm R medial orbital gyr contusion; 2 microhemorrhages (R periventricular).
4								x					SDH; SAH; nondisplaced skull fracture	L sup, mid, inf temp gyr, L fr opercular contusions; 2 microhemorrhages (L & R CGH).
5								x					Normal	2 microhemorrhages (L CGH, L sup fr gyr)
6			x										Normal	3 microhemorrhages (R genu, L sup fr gyr)
7									x				3 mm L SDH; L temp SAH	L mid and inf fr gyr, L sup and mid-temp gyr contusions; 2 microhemorrhages (L post temp, R postcentral gyr).
8		x											Small B SDH; B fr contusion; SAH	R frontal, B occ contusions; 3 microhemorrhages (B ant temp & R occ WM)
9	x												EDH; SAH; L temp contusion	R ant temp, L inf fr, R gyr rectus, R medial orbital gyr contusions; EDH
10													Normal	2 microhemorrhages (R CGH, L post temp WM)
11													Normal	2 microhemorrhages (L precentral gyr, L sup fr gyr)
12													Normal	4 microhemorrhages (L sup fr gyr, R fr operculum)
13													Normal	2 microhemorrhages (L ant and post temp WM)
14													Normal	1 microhemorrhage (R ant temp)
15													Normal	2 microhemorrhages (L sup parietal lobule)
16													Normal	2 microhemorrhages (L and R ant temp WM)
17													Small L SDH	Small L SDH

TABLE 7. (CONTINUED)

Patient	ACR Left	ACR Right	ALIC Left	ALIC Right	EC Left	EC Right	SLF Left	SLF Right	SS Left	SS Right	CGH Left	CGH Right	CT findings	Conventional MRI findings
CT/MRI-negative mTBI														
1	x												Normal	Normal
2										x			Normal	Normal
3													Nondepressed anterior skull base fracture	Normal
4													Normal	Normal
5													Normal	Normal
6													Normal	Normal
7													Normal	Normal
8													Normal	Normal
9													Normal	Normal
10													Normal	Normal
11													Normal	Normal
12													Normal	Normal
13													Normal	Normal
14													Normal	Normal
15													Normal	Normal
16													Normal	Normal
17													Normal	Normal
18													Normal	Normal
19													Normal	Normal
20													Normal	Normal
Mean FA (controls)	0.56	0.55	0.65	0.64	0.53	0.51	0.57	0.55	0.64	0.63	0.67	0.64		
Mean FA −2.2 SDs	0.50	0.49	0.60	0.59	0.48	0.46	0.50	0.50	0.58	0.57	0.57	0.53		

MRI, magnetic resonance imaging; DTI, diffusion tensor imaging; CT, computed tomography; mTBI, mild traumatic brain injury; ACR, anterior corona radiata; ALIC, anterior limb internal capsule; EC, external capsule; SLF, superior longitudinal fasciculus; SS, sagittal striatum; CGH, cingulum (parahippocampal gyrus); SDH, subdural hematoma; SAH, subarachnoid hemorrhage; L, left; R, right; B, bilateral; EDH, epidural hematoma; WM, white matter; sup, superior; mid, middle; inf, inferior; ant, anterior; post, posterior; fr, frontal; temp, temporal; occ, occipital; gyr, gyrus; SD, standard deviation; ROI, region of interest.

■ Extraaxial collection only
■ Microhemorrhage(s)
■ Contusion(s)
■ Contusion(s) + microhemorrhage(s)
Color table is available online at www.liebertpub.com/neu

TABLE 8. DTI REGION-OF-INTEREST (ROI) ANALYSIS: GROUP DIFFERENCES IN PRESENCE OF ONE OR MORE
ABNORMAL ROIS AMONG CT/MRI-NEGATIVE mTBI AND CT/MRI-POSITIVE mTBI WITHOUT NEUROPSYCHIATRIC
OR SUBSTANCE ABUSE HISTORY AND CONTROL SUBJECTS

	CT/MRI-negative mTBI (20 subjects)	CT/MRI-positive mTBI (17 subjects)	Controls (50 subjects)
	Number of subjects (Proportion of subjects)	Number of subjects (Proportion of subjects)	Number of subjects (proportion of subjects)
One or more ROIs with FA more than 2.2 SDs below control-group mean	2 (10.0%)[a]	9 (52.9%)[b]	5 (10.0%)[a]
One or more ROIs with FA more than 2.2 SD above control-group mean	3 (15.0%)[c]	1 (5.9%)[c]	5 (10.0%)[c]

[a,b,c]Each superscript denotes a subset of participants whose column proportions do not differ significantly from one another, by Fisher's exact test with $p < 0.05$. Row 1: There was a significant difference between the proportions of CT/MRI-positive (52.9%) and CT/MRI-negative mTBI patients (10.0%) with one or more ROIs with FA more than 2.2 SDs below the control group mean ($p = 0.0097$). There was also a highly significant difference between CT/MRI-positive mTBI patients (52.9%) and controls (10.0%; $p = 0.0006$). However, there was no difference between CT/MRI-negative mTBI patients (10.0%) and controls (10.0%; $p = 1.0$). Row 2: There was no significant difference among the proportions of CT/MRI-negative mTBI (15.0%), CT/MRI-positive mTBI (5.9%), and control subjects (10.0%) with one or more ROIs with FA more than 2.2 SDs above the control group mean ($p = 0.75$).

CT, computed tomography; MRI, magnetic resonance imaging; DTI, diffusion tensor imaging; ROI, region of interest; mTBI, mild traumatic brain injury; FA, fractional anisotropy; SD, standard deviation.

socioeconomic, and clinical variables were thus excluded from Table 9 for brevity. Similarly, 6-month TMT A (both age-adjusted z-score and the dichotomized score), TMT B (z-score), CVLT-II (both age-adjusted scaled score and dichotomized score), and WAIS-IV PSI (both age-adjusted scaled score and dichotomized score) were also omitted from Table 9 because they demonstrated no other significant correlation with any other imaging, clinical, demographic, or socioeconomic predictor at $p < 0.05$.

Table 9 shows that among the imaging predictors, no CT feature (CT evidence of nondepressed skull fracture, EDH, SDH, SAH, or contusion) was significantly correlated with any outcome measure at $p < 0.05$. In contrast, several MRI features, including MRI evidence of contusion, MRI evidence of hemorrhagic axonal injury, and presence of abnormally reduced FA in at least one ROI, demonstrated statistically significant correlations with several outcome measures (3- and 6-month GOS-E, abnormal 6-month TMT B, and the 6-month RPQ-13).

Discussion

In the current study, white matter FA was significantly reduced in CT/MRI-positive, but not in CT/MRI-negative, mTBI patients, compared to healthy control subjects, on a group level. In addition, regions of reduced FA in individual mTBI patients were modest, but statistically significant, predictors of unfavorable 3- and 6-month outcome. These results held true for both the inclusive sample of 76 mTBI patients as well as the subset of 37 mTBI patients with no history of previous substance abuse or other neuropsychiatric disorder.

Previous studies have reported evidence of white matter injury on DTI in the acute-to-subacute time period after mTBI.[15–18,20,23–25,27–31,34–36] In essentially all of these studies, patients with history of substance abuse or other neuropsychiatric disorders were excluded. In addition, in nearly all of these studies, the mTBI study population included a mixed group of both CT/MRI-positive and -negative mTBI, based on presence of intracranial abnormalities on CT alone, CT and 1.5T MRI, or CT and 3T MRI. Miles and colleagues[31] found, using an ROI approach, reduced average FA and increased average MD within six ROIs in a group-wise comparison of 17 mTBI patients, studied within 10 days of injury at 1.5T MRI and with no evidence of microhemor-

rhages, to 29 age- and gender-matched controls. In contrast, Ling and colleagues[24] found increased FA and decreased RD, within the callosal genu, in a mixture of 28 CT/MRI-negative and -positive mTBI patients who underwent MRI 15.6 ± 4.3 days after injury. Messe and colleagues,[30] using a whole-brain voxelwise approach to study a mixture of CT/MRI-negative and -positive mTBI patients, found higher MD values in poor-outcome patients, compared to good-outcome patients and controls, in the corpus callosum, right anterior thalamic radiations, superior longitudinal fasciculus, and inferior longitudinal and fronto-occipital fasciculi at 7–28 days after injury. Lange and colleagues,[23] using an ROI approach, found no significant difference in FA or MD in the genu, body, or splenium of the corpus callosum in 60 CT/MRI-positive and -negative mTBI patients (on the more severe end of the mTBI spectrum), relative to 34 trauma controls. A smaller number of studies[20,25,27,35] has reported statistically significant group-wise or individual FA differences in the acute-to-subacute time period in strictly CT/MRI-negative mTBI patients versus controls. For example, Lipton and colleagues, using a whole-brain voxelwise approach, found reduced FA in multiple white matter regions at 2–14 days postinjury in 20 CT/MRI-negative mTBI patients, compared to 20 age- and gender-matched controls.[27] McAllister and colleagues[56] found a statistically significant correlation between mean and maximum strain rate (based on measurements from instrumented helmets and finite element biomechanical simulation) and increased FA in the corpus callosum within the first 10 days after concussion in athletes with normal conventional brain MRI.

From the above, it is evident that DTI analysis techniques have varied between more data-driven, whole-brain voxel-wise analyses and hypothesis-driven ROI approaches. In addition, although nearly all studies have employed group-comparison designs, some investigators have chosen to compare mTBI patients to healthy controls (in some cases, matched by age, gender, and/or education), whereas others have compared mTBI subgroups with good versus poor outcome. These earlier studies, most of which are limited by small sample sizes, have also not analyzed DTI results in the context of important clinical, demographic, and socioeconomic factors relevant to TBI outcomes. Finally, there is a persistent and striking inconsistency across different DTI studies, in terms of the reported direction of changes in DTI measures after mTBI.

Whole-brain voxel-wise approaches may have limited sensitivity as a result of the heterogeneity of spatial distribution of white matter

TABLE 9. SPEARMAN'S CORRELATION COEFFICIENTS (ρ) BETWEEN OUTCOME MEASURES AND EARLY NEUROIMAGING PATHOANATOMIC FINDINGS IN 37 mTBI PATIENTS WITHOUT PREVIOUS HISTORY OF SUBSTANCE ABUSE OR OTHER NEUROPSYCHIATRIC DISORDER[a]

	Day-of-injury head CT						Early brain MRI (10.9±3.6 days postinjury)			
	Nondepressed calvarial or skull base fracture	EDH	SDH	SAH	Any CT Contusion	Any acute traumatic intracranial CT finding	Any MRI contusion	Any MRI T2* hemorrhagic axonal injury	Any DTI axonal injury (≥1 ROI with FA > 2.2 SDs below control-group mean)	Any conventional MRI and/or DTI lesion
3-month GOS-E (N=32)	−0.15 p=0.40 (4 positive)	−0.05 p=0.78 (1 positive)	−0.24 p=0.19 (5 positive)	−0.28 p=0.12 3 (positive)	−0.28 p=0.12 (5 positive)	−0.24 p=0.19 (5 positive)	−0.47 p=0.006* (5 positive)	−0.41 p=0.02 (12 positive)	−0.50 p=0.004† (10 positive)	−0.37 p=0.04* (14 positive)
6-month GOS-E (N=30)	−0.06 p=0.75 (3 positive)	−0.06 p=0.76 (1 positive)	−0.21 p=0.26 (3 positive)	−0.08 p=0.67 (2 positive)	−0.21 p=0.26 (2 positive)	−0.21 p=0.26 (3 positive)	−0.22 p=0.25 (4 positive)	−0.29 p=0.12 (11 positive)	−0.30 p=0.11 (7 positive)	−0.39 p=0.03* (13 positive)
Abnormal TMT A (>2 SDs above mean) at 6 months (N=27)	−0.14 p=0.50 N=2 (2 positive)	−0.09 p=0.64 (1 positive)	−0.17 p=0.40 (3 positive)	−0.14 p=0.50 N=27 (2 positive)	−0.14 p=0.50 (2 positive)	−0.17 p=0.40 N=27 (3 positive)	−0.20 p=0.32 (4 positive)	0.01 p=0.97 (11 positive)	0.15 p=0.45 (7 positive)	0.11 p=0.57 (13 positive)
Abnormal TMT B (>2 SDs above mean) at 6 months (N=27)	−0.17 p=0.40 (2 positive)	−0.12 p=0.56 (1 positive)	0.06 p=0.77 (3 positive)	0.16 p=0.44 (2 positive)	−0.17 p=0.40 (2 positive)	0.06 p=0.77 (3 positive)	0.23 p=0.25 N=27 (4 positive)	0.20 p=0.32 N=27 (11 positive)	0.42 p=0.03* N=27 (7 positive)	0.28 p=0.16 N=27 (13 positive)
6-month RPQ-3 (N=30)	−0.10 p=0.60 (3 positive)	−0.21 p=0.26 (1 positive)	0.13 p=0.48 (3 positive)	−0.02 p=0.90 (2 positive)	0.03 p=0.87 (2 positive)	0.13 p=0.48 (3 positive)	0.27 p=0.15 (4 positive)	0.32 p=0.09 (11 positive)	0.12 p=0.54 (7 positive)	0.23 p=0.22 (13 positive)
6-month RPQ-13 (N=30)	−0.06 p=0.74 (3 positive)	−0.13 p=0.50 (1 positive)	0.22 p=0.25 (3 positive)	0.04 p=0.84 (2 positive)	0.13 p=0.49 (2 positive)	0.22 p=0.25 (3 positive)	0.22 p=0.25 (4 positive)	0.62 p=0.0003† (11 positive)	0.40 p=0.03* (7 positive)	0.61 p=0.0004† (13 positive)

[a]The only statistically significant pair-wise correlations between any demographic, clinical or socioeconomic predictor and worse performance on any outcome variable were between years of education and TMT B z-score ($\rho = -0.50$; $p=0.007$), age and TMT A z-score ($\rho = -0.39$; $p=0.04$), and PTA duration and TMT A z-score ($\rho=0.48$; $p=0.014$). Thus, for brevity, all demographic, clinical, and socioeconomic predictors (Supplementary Table 2) (see online supplementary material at http://www.liebertpub.com) are omitted from Table 9. Similarly, 6-month TMT A (both z-score and dichotomized score), TMT B (z-score), CVLT-II (scaled score and dichotomized score), and WAIS-IV PSI (scaled score and dichotomized score) were omitted from Table 9, because they demonstrated no other significant correlation with any imaging, clinical, demographic, or socioeconomic predictor at $p<0.05$. *$p<0.05$ (light-gray boxes); †$p<0.01$ (dark-gray boxes).

CVLT-II, California Verbal Learning Test–Second Edition; EDH, epidural hematoma; SDH, subdural hematoma; SAH, subarachnoid hemorrhage; DTI, diffusion tensor imaging; ROI, region of interest; SD, standard deviation; FA, fractional anisotropy; GOS-E, Glasgow Outcome Scale-Extended; TMT, Trail Making Test; RPQ, Rivermead Postconcussion Questionnaire; CVLT, California Verbal Learning Test; WAIS-IV PSI, Wechsler Adult Intelligence Scale–Fourth Edition, Processing Speed Index.

injury in mTBI; on the other hand, the ROI approach may be limited by failure to interrogate less-common areas of white matter injury. We employed both of these as complementary approaches in the current study and demonstrated that microstructural white matter injury severity does vary, on a group level, according to the presence of more-familiar macroscopic pathoanatomic lesions on CT and conventional MRI. It may not be surprising that the data show that CT/MRI-positive mTBI patients have more extensive white matter injury than CT/MRI-negative mTBI patients. However, such work is relevant because any utility of DTI in outcome prediction would be contingent on demonstration of a differential increase in diagnostic or prognostic accuracy beyond conventional CT and MRI as well as clinical, demographic, and socioeconomic predictors.

In this study of 76 mTBI patients and 50 control subjects, and using current DTI acquisition and postprocessing techniques, CT/MRI-positive mTBI patients demonstrated evidence of white matter injury when employing either whole-brain voxel-wise or ROI approaches. Indeed, we found no evidence for white matter injury, using either the whole-brain voxel-wise or ROI methods, in mTBI patients without lesions on CT or 3T MRI that included high-resolution 3D T1- and T2-weighted sequences as well as T2*-weighted gradient echo sequences. These findings held true in both the inclusive group of 76 mTBI patients, as well as the subset of 37 patients with no previous history of substance abuse or other neuropsychiatric disorders. There are several possible reasons for the discrepancy between our results with a few earlier studies demonstrating statistically significant FA differences on acute-to-sub-acute 3T DTI between strictly CT/MRI-negative mTBI patients and controls.[20,25,27,35] Technical differences in DTI acquisition or DTI postprocessing techniques could always be an explanation for such differences. The effect size and incidence of white matter injury in CT/MRI-negative mTBI may be too small, or the severity and/or spatial distribution too variable among patients, to show statistically significant group differences based on the number of patients and analysis approach employed in the current study. The injury-to-MRI interval may be a critical factor; it has been postulated that a variety of different biological processes within injured white matter may vary not only according to injury severity, but also at different time intervals after injury, and that FA, in particular, may be abnormally increased within the first week of injury.[16,18,29,35,36] Patients in the current study underwent MRI during the first 3 weeks after injury (11.2 ± 3.3 days), when different biological processes and thus DTI parameters may still have been evolving. Finally, it is possible that our results differ because many cases of CT/MRI-positive mTBI in this study were placed in that group on the basis of very subtle MRI lesions at 3T, such as one or two subtle isolated foci of hemorrhagic axonal injury, and may have been classified as uncomplicated mTBI in other studies. This third explanation has the appeal of being compatible with earlier literature that reports DTI evidence of white matter injury in subjects classified as uncomplicated mTBI based on CT alone.[15,16,18,36] Another main aim of this work was to investigate the utility of DTI parameters as predictors of individual outcome. We thus determined and compared ORs for a variety of demographic, socioeconomic, clinical, and imaging predictors, including DTI parameters. Our data suggest that MRI predictors, particularly MRI evidence of contusion and DTI evidence of one or more ROIs with reduced FA, and clinical and socioeconomic predictors, including education and previous history of neuropsychiatric disorder, surpass most CT features for prediction of most 3- and 6-month outcome measures.

Analysis of the subset of mTBI patients without a previous history of substance abuse and/or neuropsychiatric disease (Fig. 2; Tables 7–9 and Supplementary Tables 2 and 3) (see online supplementary material at http://www.liebertpub.com) is informative, because it addresses the problem of a possible strong confounding influence of these pre-existing conditions owing to their potential relationships with *both* DTI parameters and outcome. In this subset analysis, it was actually necessary to separate CT/MRI-positive from CT/MRI-negative mTBI patients to see any evidence of white matter injury using either the whole-brain voxel-wise or ROI approaches. Specifically, the whole-brain voxel-wise analysis (Fig. 2) and ROI analysis (Tables 7 and 8) both demonstrate differences between CT/MRI-positive and -negative mTBI patients that are even more striking and statistically significant than in the original analysis of the inclusive group of 76 mTBI patients. Table 8 shows a strikingly higher prevalence of abnormal ROIs with reduced FA in CT/MRI-positive patients without previous history of substance abuse or other neuropsychiatric disorders, relative to both the CT/MRI-negative mTBI patients ($p = 0.004$) and the control group ($p = 0.0002$); in contrast, the same prevalence of abnormal ROIs with reduced FA was observed in CT/MRI-negative patients (10.0%) and in the control group (10.0%).

It is noteworthy that both conventional MRI and DTI predictors demonstrated stronger correlation coefficients with 3- and 6-month outcome measures in the *subset* of 37 patients lacking any history of neuropsychiatric disease or substance abuse (Table 9) than in the larger inclusive sample of 76 patients (Table 5), despite the much smaller sample size of the former. We postulate that this is because correlations of pre-existing factors, such as neuropsychiatric disease, with the outcome measures (e.g., in Table 5) may have weakened the apparent influence or relevance of the imaging predictors.

It is also notable that there were generally much stronger correlations of MRI predictors with 3-month GOS-E than with 6-month GOS-E. This is plausible, because the MRI exams in this study were performed within 3 weeks after mTBI. Abnormal MRI features in the initial days after injury, which demonstrated a strong correlation with 3-month GOS-E, may be less relevant at 6 months, after a variable degree of recovery has taken place in different patients. The stronger correlation with the GOS-E at 3 months, compared to 6 months, is unlikely to be attributable solely to general overall improvement in the GOS-E over time: Though many individual patients' scores changed between the two time points, there was negligible change in the overall distribution of GOS-E scores at 3 versus 6 months (Table 4 and Supplementary Table 3) (see online supplementary material at http://www.liebertpub.com).

In this study, we sought to minimize the influence of confounding factors on group differences in DTI parameters between patient and control groups. Thus, we did not follow the approach of presorting patients according to an outcome measure, and thereafter assessing for group differences in DTI results according to good or poor outcome, because there are many potential confounding factors that could affect both DTI measures and outcome. Further, we analyzed, in addition to the original inclusive sample, the subset of patients lacking any significant reported substance abuse or other neuropsychiatric history, because these pre-existing conditions are heterogeneous by nature and thus difficult to control for in group comparisons and could act as confounding variables that could create or exacerbate group differences in DTI measures. Finally, because there was a nonsignificant, but noticeable, difference in number of years of education among CT/MRI-positive mTBI, CT/MRI-negative mTBI, and control groups, we explicitly demonstrated that there were no group differences in DTI measures, using either the DTI or ROI approach, between the most- and least-educated control subjects.

This study has several limitations. Alteration of DTI parameters in TBI has been linked to a variety of possible pathophysiological mechanisms, such as axonal disruption, axonal degeneration, and cytotoxic edema; recent work also suggests that DTI parameters, such as FA and MD, may be correlated with strain and strain rate in mTBI.[56] Nevertheless, despite our attempt, in performing the subset analysis, to minimize or eliminate the influence of confounding factors that could account for both DTI lesions and poorer outcome, we acknowledge that lesions in the DTI ROI analysis are nonspecific and may reflect the patient's pre-existing brain structure, rather than a traumatic lesion.[33] Second, a substantial unexplained variance in outcomes remains, even for our most inclusive models that were based on DTI, conventional neuroimaging, and other predictors (Table 6). Third, because the number of predictors we investigated was large, relative to the number of patients, this study should be regarded as exploratory and in need of confirmation in a larger study population. Finally, even for pathoanatomic findings, such as contusion and SAH, that can be definitively attributed to acute TBI based on their unique imaging appearance, the existence of any direct pathophysiological mechanism that accounts for their correlation with outcome remains uncertain.

In summary, this study provides evidence for the importance of individual pathoanatomic features on MRI, including DTI parameters, for prognosis after mTBI. Specifically, several MRI predictors, including DTI parameters, surpassed CT features for prediction of 3- and 6-month outcome measures. For the subset of patients lacking any significant neuropsychiatric or substance abuse history, MRI predictors, including DTI parameters, surpassed all clinical, demographic, socioeconomic, and CT features for prediction of 3- and 6-month outcome. Our results should be viewed as relevant primarily to mTBI patients who meet ACEP/CDC ED criteria for head CT and who thus generally have more severe injuries than mTBI patients who are not triaged to head CT. Our results support the potential utility of MRI and DTI in the acute/subacute stage of acute mTBI for better classification of injury severity. Effective, practical imaging markers that identify mTBI patients who will have unfavorable outcome are essential for clinical trials to evaluate treatments and for better triage to effective follow-up care.

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Author Disclosure Statement

No competing financial interests exist

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Outcome Prediction after Mild and Complicated Mild Traumatic Brain Injury: External Validation of Existing Models and Identification of New Predictors Using the TRACK-TBI Pilot Study

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Abstract

Although the majority of patients with mild traumatic brain injury (mTBI) recover completely, some still suffer from disabling ailments at 3 or 6 months. We validated existing prognostic models for mTBI and explored predictors of poor outcome after mTBI. We selected patients with mTBI from TRACK-TBI Pilot, an unselected observational cohort of TBI patients from three centers in the United States. We validated two prognostic models for the Glasgow Outcome Scale Extended (GOS-E) at 6 months after injury. One model was based on the CRASH study data and another from Nijmegen, The Netherlands. Possible predictors of 3- and 6-month GOS-E were analyzed with univariate and multi-variable proportional odds regression models. Of the 386 of 485 patients included in the study (median age, 44 years; interquartile range, 27–58), 75% ($n = 290$) presented with a Glasgow Coma Score (GCS) of 15. In this mTBI population, both previously developed models had a poor performance (area under the receiver operating characteristic curve, 0.49–0.56). In multivariable analyses, the strongest predictors of lower 3- and 6-month GOS-E were older age, pre-existing psychiatric conditions, and lower education. Injury caused by assault, extracranial injuries, and lower GCS were also predictive of lower GOS-E. Existing models for mTBI performed unsatisfactorily. Our study shows that, for mTBI, different predictors are relevant as for moderate and severe TBI. These include age, pre-existing psychiatric conditions, and lower education. Development of a valid prediction model for mTBI patients requires further research efforts.

Key words: GOS-E; prognostic models; TBI; validation

Introduction

TRAUMATIC BRAIN INJURY (TBI) IS AMONG THE LEADING causes of death and disability. In the United States, at least 1.7 million patients a year seek some form of medical treatment.[1] TBI exacts significant health, social, and economic hardships on patients, their families, and health systems.[2,3] Approximately 70–90% of all TBIs are categorized as mild (mTBI), that is, presenting with a Glasgow Coma Scale (GCS) score of 13–15 after nonpenetrating head trauma. Although most mTBI patients will recover without residual impairments, persistent sequelae remain in a subgroup of 5–15%.[4] These complaints may include physical symptoms, behavioral disturbances,

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and cognitive dysfunction, any of which may interfere with return to work or resumption of social activities. Prognostic analyses are essential to identify patients at increased risk of developing residual sequelae and for leveraging resources to follow a more risk-prone subgroup. Closer observation and early intervention as part of clinical practice may alleviate the psychological burden of injury on these patients, as well as the related economic burden on society.

The heterogeneity in case definition of mTBI, the variety of outcome measures, and the variability in time elapsed for scoring both predictors and outcome render interpretation and comparison of results from mTBI prognostic studies difficult. Further, most studies only report on the association between predictors and outcome in univariate analyses.[5,6]

To our knowledge, only two studies have combined predictors and developed a prediction model specifically for mTBI.[7,8] One other model (Corticosteroid Randomization After Significant Head Injury; CRASH) was developed on patients with GCS 3–14 and thus captured a segment of the mTBI population, but not patients with GCS 15.[9,10] Further, none of the models have been externally validated in mTBI. Before a prognostic model can reliably be applied to clinical practice, external validation is required to determine generalizability. In this study, we aimed to evaluate the performance of existing mTBI prognostic models using a recent, prospective, unselected population of mTBI patients enrolled across three level 1 trauma centers in the United States and explore relevant predictors of poor outcome after mTBI.

Methods

Patient population

The study population consisted of patients included in the **T**ransforming **R**esearch **a**nd **C**linical **K**nowledge in TBI (TRACK-TBI) Pilot study.[11] In this study TBI patients age >16 years were enrolled upon arrival in the emergency departments (EDs) at San Francisco General Hospital (University of California San Francisco; UCSF), University of Pittsburgh Medical Center, and University Medical Center Brackenridge. All participants or their legally authorized representatives gave written informed consent. At follow-up outcome assessments, participants previously consented by legally authorized representative, if neurologically improved and capable, were consented for continuation in the study.

Inclusion criteria were presentation to study hospital within 24 h of injury and history of trauma to the head sufficient to triage to noncontrast head computed tomography (CT) using the American College of Emergency Physicians/Centers for Disease Control evidence-based joint practice guidelines.[12] We selected patients with mTBI and available 3- or 6-month outcome. All study protocols were approved by the institutional review boards at each participating level 1 trauma center.

Measures

Details on loss of consciousness, amnesia, and source of trauma were recorded upon admission and informed consent was obtained. GCS score was assessed by a neurosurgeon at admission.[13] Trained study personnel in the ED obtained demographic data, patient history, and clinical information from the patient. All patients underwent CT imaging at the time of initial presentation to the ED. Each patient's head CT was characterized using the National Institutes of Health/National Institute of Neurological Disorders and Stroke TBI Common Data Elements (TBI-CDEs).[14–16] Clinical brain CTs were transmitted to a radiology picture-archiving and communications system with software that allow controlled remote access for multiple users at study sites. To comply with the Health Insurance Portability and Accountability Act of 1996, the UCSF Quantitative

Image Processing Center built a multiplatform tool that completely anonymized CT studies during the transmission process. Each CT was then reviewed by a single board-certified neuroradiologist blinded to demographic, socioeconomic, and clinical data, except gender and age, and scored on 26 of the 93 CDEs developed by the TBI-CDE neuroimaging working group.[17,18]

Outcome

The outcomes for this study were the Glasgow Outcome Scale Extended (GOS-E) at 3 and 6 months after injury.[19] The GOS-E provides eight categories of outcome: dead; vegetative state; lower severe disability; upper severe disability; lower moderate disability; upper moderate disability; lower good recovery; and upper good recovery. Ratings are based on patient consciousness, independence, ability to work, social and leisure activities, social relationships, and other sequelae of TBI. Upper good recovery (GOS-E score of 8) indicates return to preinjury baseline with no residual effects of the TBI.

Prediction models

Our literature search identified three prediction models that were developed (partly) on mTBI patients.[7–9] We could not validate the Stuhlemeijer and colleagues model because not all of the former's predictors were available in our data set.[7] We thus undertook to validate the Nijmegen and CRASH models.[9] The characteristics of the model are described in Table 1.

The Nijmegen model was built specifically for mTBI, with 6-month GOS-E < 7 as the endpoint. Multivariable analysis of 1069 patients with GOS-E yielded age, Abbreviated Injury Score for head (AISh), Injury Severity Score (ISS) without head, and alcohol intoxication as significant predictors in the clinical model and number of hemorrhagic contusions and facial fractures as predictors of unfavorable outcome in the CT model and age, ISS without head, number of hemorrhagic contusions, and alcohol intoxication in the combined model.[8]

The Medical Research Council CRASH trial built and externally validated two prognostic models in mild, moderate, and severe TBI.[9] A basic model included age, GCS, pupillary reactivity, and presence of extracranial injury. In a CT model, additionally included were petechial hemorrhage, obliteration of third ventricle and cisterns, subarachnoid hemorrhage (SAH), mid-line shift, and nonevacuated hematoma emerged as predictors for mortality at 14 days and unfavorable outcome on the GOS (<4) at 6 months postinjury.[9] In this study, we only validated the models for 6-month unfavorable outcome. We note that the CRASH model excluded patients with GCS 15, a score that represents a majority of this subpopulation.

Statistical analysis

If patients had a missing outcome at 6 months, but an observed outcome at 3 months, the 3-month value was extrapolated to 6 months. Similarly, 6-month outcomes were interpolated when 3-month outcome was missing. Patients with missing outcome at both time points were excluded. Missing values in predictors were statistically imputed using single imputation with the AregImpute function in R statistical software (version 2.14; R Foundation for Statistical Computing, Vienna, Austria).

Patients' baseline characteristics were described by median and interquartile range (IQR) for continuous variables and frequencies and percentages for categorical variables. These descriptive statistics were reported on the nonimputed data.

The prediction models were applied to the patients in the validation set, that is, a predicted probability of unfavorable outcome was calculated for each patient using the CRASH and Nijmegen models. Accordingly, the external validity of the models was assessed by studying calibration and discrimination. Calibration refers to the agreement between observed and predicted outcomes. The

TABLE 1. CHARACTERISTICS OF THE VALIDATED MODELS

Model	Development population (n)	Predictors	Outcome
Nijmegen Clinical model	GCS 13–15 (n = 1069)	-Age -AIS head -ISS without head -Alcohol intoxication	6-month GOS-E < 7
CT model		-Number of hemorrhagic contusions -Facial fractures	
Combined model		-Age -ISS without head -Number of hemorrhagic contusions -Alcohol intoxication	
CRASH Basic model	GCS 3–14 (n = 10,008)	-Age -GCS -Pupillary reactivity -Extracranial injury	6-month GOS < 4
CT model		Basic model plus -Petechial hemorrhage -Obliteration of third ventricle and cisterns -Subarachnoid hemorrhage -Mid-line shift -Nonevacuated hematoma	

CT, computed tomography; CRASH, Corticosteroid Randomization After Significant Head Injury; GCS, Glasgow Coma Scale; AIS, Abbreviated Injury Score; ISS, Injury Severity Score; GOS-E, Glasgow Outcome Score Extended.

extent of over- or underestimation, relative to the observed and predicted rate, was explored graphically using validation plots.[20] We assessed calibration-in-the-large by fitting a logistic regression model with the logit of model predictions as an offset variable. The intercept indicates whether predictions are systematically too low or high and should ideally be zero. The calibration slope reflects the average effects of the predictors in the model and was estimated in a logistic regression model with the logit of the model predictions as the only predictor. For a perfect model, the slope is equal to 1. The area under the receiver operating characteristic curve (AUROC) was used to quantify the ability of the model to discriminate between patients who died versus survived. Because the development of the CRASH model did not include patients with GCS 15, we validated it both on patients with GCS 13–14 and on our total study population.

To further explore relevant predictors of 3- and 6-month GOS-E, we selected 21 possible predictors from the literature and based on clinical knowledge. These were analyzed in univariate and multi-variable proportional odds regression models with 3- and 6-month GOS-E as ordinal outcomes. This means that the full range of the GOS-E is considered instead of dichotomizing at a fixed point (e.g., favorable vs. unfavorable outcome). Simulation studies have shown that ordinal analysis is more efficient than dichotomization, also when the proportional odds assumption is violated. Each predictor was tested in the univariate models, and those with a p value of 0.30 in both the 3- and 6-month model were selected for inclusion in the multi-variable models. The liberal p value was motivated by the fact that we performed an exploratory analysis in a relatively small sample size and did not want to exclude possible predictors.

All analyses were performed with R statistical software (version 2.14; R Foundation for Statistical Computing).

Results

Patient population

TRACK-TBI Pilot enrolled 485 patients with mTBI, including 480 with nonpenetrating injury who were eligible for our study.

Patients with penetrating brain injury (n = 5) or missing outcome at both 3 and 6 months after injury (n = 94) were excluded. A total of 386 patients were included in our analysis. The median age of our population was 44 years (IQR, 27–58). The majority (n = 271; 70%) was male. Most patients (n = 290; 75%) presented with a GCS of 15 and two reactive pupils. Most patients were injured in a motor vehicle traffic accident (n = 179; 47%). Almost one third (n = 118; 31%) of the patients had self-reported psychiatric (mental health) history, which was obtained at the time of injury through patient interview using a checklist of common psychiatric conditions as defined by the TBI CDE V1.0 (e.g., anxiety, depression, sleep disorders, post-traumatic stress, bipolar disorder, schizophrenia, and others). Patients need not have been formally diagnosed with a mental health disturbance; however, to qualify as ''positive'' for psychiatric history, the patient must deem the condition to be significantly disturbing for their baseline quality of life. More then half (n = 198; 53%) of the patients reported history of previous TBI as defined by external force injury to the head. Over half of the patients (n = 232; 60%) had no visible CT pathology (Marshall's CT classification I).[21] The most common pathologies observed on CT were contusions (61; 16%), SAH (103; 27%), and facial fractures (53; 14%). Most baseline variables had very few missing values (<2%), but the AISh, ISS, and extracranial injury had almost 40% missing values. Alcohol intoxication, as measured by blood alcohol levels, was missing in almost 60% of cases (Table 2).

At 3 months after injury, 116 (24%) were lost to follow-up. Of those with observed outcomes, 33% (n = 121) completely recovered (GOS-E, 8) and 32% (n = 118) had some remaining symptoms (GOS-E, 7). Of the remaining one third of the sample 2% (n = 6) died, 4% (n = 15) were severely disabled (GOS-E, 3–4), and 28% (n = 104) were moderately disabled (GOS-E, 5–6; Table 3).

After 6 months, an additional 181 (38%) patients were lost to follow-up. Of those with observed outcome, 34% (n = 102) made a complete recovery (GOS-E, 8) at 6 months and 30% (n = 89) had

TABLE 2. PATIENT CHARACTERISTICS ($N=386^{a}$)

Characteristic	Missing	No. (%)
Age (median, IQR)	0	44 (27–58)
Male gender	0	271 (70)
Cause	4	
Road traffic accident		179 (47)
Fall		133 (35)
Assault		54 (14)
Struck by/struck against person or object		14 (6)
Other		2 (1)
GCS	0	
15		290 (75)
14		81 (21)
13		15 (4)
Pupil reactivity	61	
Both reactive		319 (98)
One reactive		5 (2)
None reactive		1 (0)
Psychiatric medical history	0	118 (31)
Hypoxia	2	23 (6)
Hypotension	1	13 (3)
Previous TBI (with and without hospital admission)	11	198 (53)
Education	12	
Low		37 (10)
Middle		202 (54)
High		135 (36)
Alcohol intoxication	228	52 (33)
ISS (median, IQR)	152	16 (10–18)
AIS head	152	
0		34 (15)
1		6 (3)
2		27 (12)
3		70 (30)
4		83 (35)
5		14 (6)
Extracranial injury	152	53 (23)
Marshall CT	0	
1		232 (60)
2		134 (35)
3		9 (2)
4		4 (1)
5		5 (1)
6		2 (1)
Facial fracture	0	53 (14)
EDH	0	12 (3)
tSAH	1	103 (27)
Mid-line shift	1	10 (3)
Third ventricle obliteration	2	11 (3)
Contusions	1	61 (16)
Petechial hemorrhage	1	3 (1)

[a]Of 485 patients, 5 were excluded because they had penetrating injury and 94 had missing outcome, leaving 386 for inclusion.

IQR, interquartile range; GCS, Glasgow Coma Scale; TBI, traumatic brain injury; ISS, Injury Severity Score; AIS, Abbreviated Injury Score; CT, computed tomography; EDH, extradural haematoma; tSAH, traumatic subarachnoid hemorrhage.

some remaining symptoms (GOS-E, 7). Three percent ($n=9$) had died, 3% ($n=9$) were severely disabled (GOS-E, 3–4), and 30% ($n=90$) were moderately disabled (GOS-E, 5–6).

Between 3 and 6 months after injury, 3 patients died and another 65 deteriorated, based on worsening GOS-E. Conversely, 66 patients showed improved GOS-E scores between 3 and 6 months. The 94 patients with missing outcome at both time points were excluded from this analysis.

Model validation

The Nijmegen models performed poorly in the external validation, with AUROCs of 0.52 (95% confidence interval [CI], 0.49–0.56; clinical model), 0.55 (95% CI, 0.49–0.55; CT model), and 0.56 (95% CI, 0.49–0.56; combined model) (Fig. 1). The CRASH models performed poorly in the total mTBI population, including GCS 15 (AUROC basic model, 0.49; 95% CI, 0.43–0.70; AUROC CT model, 0.49; 95% CI, 0.42–0.66) (Fig. 2). However, performance was very well with AUROCs of 0.90 (95% CI, 0.82–0.97; basic model) and 0.91 (95% CI, 0.85–0.98; CT model) (Fig. 3) in the population they were developed on. The proportion of unfavorable outcome in TRACK-TBI Pilot was overestimated by most models. For example, the predicted proportion of patients with unfavorable outcome by the CRASH CT model was 12%; however, the actual observation of unfavorable outcome at 6 months was 8%.

Predictors

In univariate analyses (Table 4), we identified a large number of characteristics as potential predictors of outcome both 3- and 6-month GOS-E: age; cause of injury; GCS; pupil reactivity; psychiatric medical history; hypoxia; hypotension; education; ISS; extracranial injury; SAH; mid-line shift; and third ventricle obliteration and contusions (all $p < 0.30$ for both 3- and 6-month GOS-E; Table 4). Some predictors had a different effect on 3-versus 6-month outcome. A GCS of 13 or 14 was a strong predictor for a lower 6-month GOS-E (odds ratio [OR] = 0.3; $p = 0.015$), but less predictive for lower 3-month GOS-E (OR = 0.5–0.6; $p = 0.299$). In contrast, the CT characteristics were more predictive of 3-month outcome, compared with 6-month outcome (e.g., SAH: 3-month OR = 2.2, $p < 0.001$; 6-month OR = 1.3, $p = 0.224$).

In multivariable analyses (Table 5), the strongest predictors of both lower 3- and 6-month GOS-E were older age (OR, 1.2; $p < 0.001$), history of psychiatric conditions (OR = 2.2–2.4; $p < 0.001$), and lower education (OR, 0.4–0.8; $p < 0.05$; Table 4). Injury caused by assault and extracranial injury were important predictors of poorer outcome at both time points ($p = 0.05$–0.1). Finally, a lower GCS was predictive of lower 6-month GOS-E (OR, 0.3–0.4; $p = 0.039$).

Discussion

In this study, we externally validated two prognostic models for prediction of outcome after mTBI. We found that both models performed unsatisfactorily in our validation data set. In exploratory analyses, we identified older age, pre-existing psychiatric conditions, lower education, injury caused by assault and extracranial injury, and lower GCS as predictors of 3- and 6-month GOS-E.

Study population

We included only patients with a so-called mTBI, as defined by a GCS 13–15. However, the population did contain some patients

TABLE 3. OUTCOME[a]

3-month GOS-E / 6-month GOS-E	1	2	3	4	5	6	7	8	Unknown	Total (%)
1	6	0	1	0	1	0	1	0	0	9 (3[b])
2	0	0	0	0	0	0	0	0	0	0 (0[b])
3	0	0	2	1	1	0	0	0	1	5 (2[b])
4	0	0	2	1	0	0	1	0	0	4 (1[b])
5	0	0	1	0	14	10	6	4	3	38 (13[b])
6	0	0	0	3	9	13	21	3	3	52 (17[b])
7	0	0	0	1	5	14	43	18	8	89 (30[b])
8	0	0	0	0	2	7	22	64	7	102 (34[b])
Unknown	0	0	0	3	9	19	24	32	94	181 (38[c])
Total (%)	6 (2[b])	0 (0[b])	6 (2[b])	9 (2[b])	41 (11[b])	63 (17[b])	118 (32[b])	121 (33[b])	116 (24[c])	480

[a]$n=480$.
[b]Percentage of patients with observed outcome.
[c]Percentage of all patients.
GOS-E, Glasgow Outcome Score Extended.

TABLE 4. UNIVARIATE PREDICTORS OF 3- AND 6-MONTH GOS-E[a]

Predictors	Common OR (95% CI) (3 months)	p value	Common OR (95% CI) (6 months)	p value
Age (per 10 years)	1.2 (1.1–1.3)	<0.001	1.2 (1.1–1.3)	0.002
Male gender	0.9 (0.6–1.4)	0.678	0.8 (0.6–1.2)	0.316
Cause		0.021		<0.001
MV	Ref		Ref	
Fall	1.4 (0.9–2.1)		1.6 (1.1–2.4)	
Assault	2.2 (1.3–3.6)		2.6 (1.5–4.5)	
Struck by/strike against	1.3 (0.5–3.4)		0.6 (0.2–1.7)	
GCS		0.299		0.015
13	Ref		Ref	
14	0.6 (0.3–1.6)		0.3 (0.1–1.0)	
15	0.5 (0.2–1.3)		0.3 (0.3–0.7)	
No or one pupil reactive	2.4 (0.6–9.6)	0.205	3.8 (1.1–13.5)	0.039
Psychiatric medical history	2.2 (1.5–3.3)	<0.001	2.9 (1.9–4.2)	<0.001
Hypoxia	2.8 (1.3–5.9)	0.009	2.7 (1.2–6.1)	0.018
Hypotension	1.8 (0.7–4.8)	0.206	2.2 (0.8–5.8)	0.112
Education		0.050		0.012
Low	Ref		Ref	
Middle	1.0 (0.5–1.9)		0.7 (0.4–1.4)	
High	0.6 (0.3–1.1)		0.4 (0.2–0.8)	
Alcohol intoxication	0.9 (0.6–1.3)	0.565	1.2 (0.8–1.7)	0.463
ISS	1.03 (1.01–1.06)	0.026	1.02 (0.99–1.04)	0.156
AIS head	1.2 (1.0–1.3)	0.017	1.03 (0.90–1.12)	0.701
Extracranial injury	1.7 (1.1–2.7)	0.012	1.6 (1.0–2.4)	0.044
Marshall's CT		0.002		0.836
1	Ref		Ref	
2	1.9 (1.3–2.8)		1.0 (0.8–1.5)	
3–4	2.9 (1.2–7.6)		1.7 (0.7–4.1)	
5–6	15.5 (3.2–76.2)		8.5 (1.8–40.8)	
Facial fracture	1.4 (0.9–2.4)	0.147	1.3 (0.8–2.3)	0.307
EDH	1.0 (0.4–2.6)	0.986	0.3 (0.1–0.9)	0.033
tSAH	2.2 (1.5–3.3)	<0.001	1.3 (0.9–1.9)	0.224
Midline shift	7.8 (2.2–27.6)	0.013	3.2 (0.9–11.6)	0.070
Third ventricle obliteration	8.2 (2.6–26.4)	<0.001	3.2 (1.0–10.3)	0.050
Contusions	1.9 (1.2–3.1)	0.008	1.4 (0.9–2.3)	0.171
Petechial hemorrhage	2.0 (0.3–12.7)	0.473	0.5 (0.1–3.5)	0.527

[a]$n=386$.
GOS-E, Glasgow Outcome Score Extended; MV, motor vehicle; GCS, Glasgow Coma Scale; ISS, Injury Severity Score; AIS, Abbreviated Injury Score; CT, computed tomography; EDH, extradural haematoma; tSAH, traumatic subarachnoid hemorrhage; OR, odds ratio, CI, confidence interval; Ref, reference.

TABLE 5. MULTIVARIABLE PREDICTORS OF 3- AND 6-MONTH ORDINAL GOS-E

Predictor	Common OR (95% CI) (3 months)	p value	Common OR (95% CI) (6 months)	p value
Age (per 10 years)	1.2 (1.1–1.4)	<0.001	1.2 (1.1–1.4)	<0.001
Cause		0.103		0.039
MV	Ref		Ref	
Fall	0.9 (0.6–1.4)		1.0 (0.6–1.6)	
Assault	1.9 (1.1–3.4)		2.0 (1.1–3.6)	
Struck by/strike against	1.1 (0.4–3.4)		0.5 (0.2–1.4)	
GCS		0.481		0.061
13	Ref		Ref	
14	0.8 (0.3–2.3)		0.4 (0.1–1.2)	
15	0.6 (0.2–1.7)		0.3 (0.1–0.9)	
No or one pupil reactive	1.0 (0.2–4.4)	0.974	2.1 (0.6–7.5)	0.253
Psychiatric medical history	2.2 (1.4–3.2)	<0.001	2.4 (1.6–3.7)	<0.001
Hypoxia	2.0 (0.9–4.4)	0.101	1.8 (0.7–4.2)	0.193
Hypotension	1.4 (0.5–3.6)	0.507	1.6 (0.6–4.1)	0.369
Education		0.032		0.016
Low	Ref		Ref	
Middle	0.8 (0.4–1.6)		0.7 (0.4–1.4)	
High	0.5 (0.2–1.0)		0.4 (0.2–0.9)	
ISS per point	1.02 (0.99–1.04)	0.250	1.00 (0.98–1.03)	0.759
Extracranial injury	1.7 (1.0–2.7)	0.045	1.5 (0.9–2.4)	0.105
tSAH	1.6 (0.9–2.9)	0.095	0.9 (0.5–1.5)	0.579
Mid-line shift	1.6 (0.3–8.6)	0.594	0.8 (0.1–5.2)	0.844
Contusion	1.3 (0.7–2.6)	0.404	1.6 (0.8–3.1)	0.176
Third ventricle obliteration	4.1 (0.8–20.6)	0.084	3.4 (0.6–20.2)	0.181

AUROC 3-month model = 0.68; AUROC 6-month model = 0.69.

GOS-E, Glasgow Outcome Score Extended; MV, motor vehicle; GCS, Glasgow Coma Scale; ISS, Injury Severity Score; tSAH, traumatic subarachnoid hemorrhage; OR, odds ratio, CI, confidence interval; Ref, reference.

with one or two unreactive pupils, an AISh of 4 or 5, or a Marshall's CT classification of 5 or 6, characteristics that indicate a more severe head injury. This illustrates the limitations of a unidimensional approach to classification of TBI. More than half of the patients reported a previous head injury. This might be an overestimation given that it was self-reported.

Outcome

Our findings that one third of the patients made a complete recovery (GOS-E, 8), one third had some minor remaining symptoms (GOS-E, 7), and the final one third had significant disabling complaints at 3 and even 6 months are consistent with previous research.[7] Although our study population might include somewhat more severe patients than the general population as a result of the case mix at our level 1 trauma enrollment centers, these results illustrate that the consequences of mTBI should not be underestimated. The overall outcome distribution was similar at 3 and 6 months, but there were some patients who died between 3 and 6 months and some that deteriorated. Unfortunately, we were unable to trace whether those that deteriorated did so as a result of the initial head injury or from other events. The lost to follow-up percentage increased to 38% at 6 months. This lost to follow-up percentage is similar to, or better than, other TBI studies.[22–24] However, higher follow-up rates are generally achieved in randomized, controlled trials. TBI patients are a difficult group to follow, and researchers should recognize the fact that it requires substantial resources to achieve acceptable follow-up rates in TBI studies.

Approximately half of the patients (94 of 181) who were lost to follow-up at 6 months also did not have a 3-month outcome. Of the patients with observed outcome at 3 months, the majority (56 of 87) had a GOS-E of 7 or 8. This is consistent with previous findings that willingness to participate in research is less in those who fully recover and may result in an overestimation of the rate of unfavorable outcome.[25] Given that it is unlikely that predictors have differential relative effects in patients with more-favorable outcome, we do not expect the results of the prognostic analyses to be affected by the missing outcomes.

Models

With AUROCs of 0.52–0.56, the Nijmegen model's ability to discriminate between patients with favorable and unfavorable outcome was hardly better than chance (AUROC = 0.5). The reason for this poor performance is likely to be related to the original modeling strategy used in this study. Their development sample included 1069 patients, of which 257 had unfavorable outcome. In this sample, 33 possible predictors were tested, corresponding to one predictor for seven outcome events. A rule of thumb in prognostic modeling is that at least 10–20 outcome events are required to test one predictor. Testing too many predictors for the sample size may result in models that are overfitted, resulting in a good apparent performance in the development data, but poor performance at external validation. The amount of overfitting can be assessed and quantified with internal validation (e.g., in a bootstrap procedure), but this was not done by Jacobs and colleagues. The
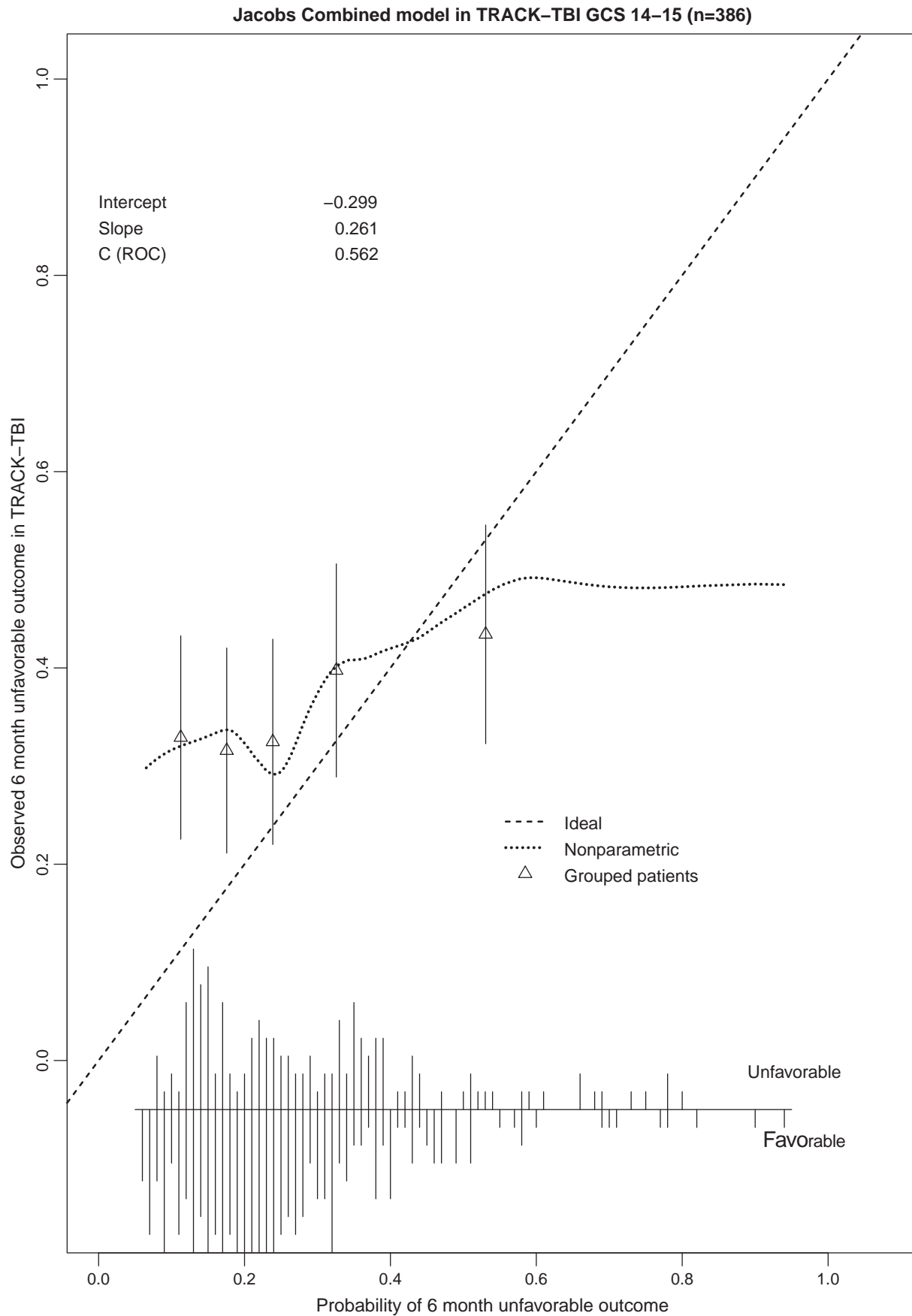
FIG. 1. Calibration plot Jacobs combined model. x-axis shows predicted probabilities by the model in quintiles of patients (triangles with horizontal lines as 95% confidence intervals); y-axis shows observed probabilities. Dotted diagonal represents perfect predictions. Spikes along the x-axis are numbers of patients with favorable and unfavorable observed outcomes. ROC, receiver operating characteristic.

CRASH CT model in TRACK−TBI GCS 13−15 (n=386)

Intercept   −2.144
Slope   0.320
C (ROC)   0.495

Observed 6 month unfavorable outcome in TRACK−TBI

- - - Ideal
······ Nonparametric
△ Grouped patients

Unfavorable

Favorable

Probability of 6 month unfavorable outcome
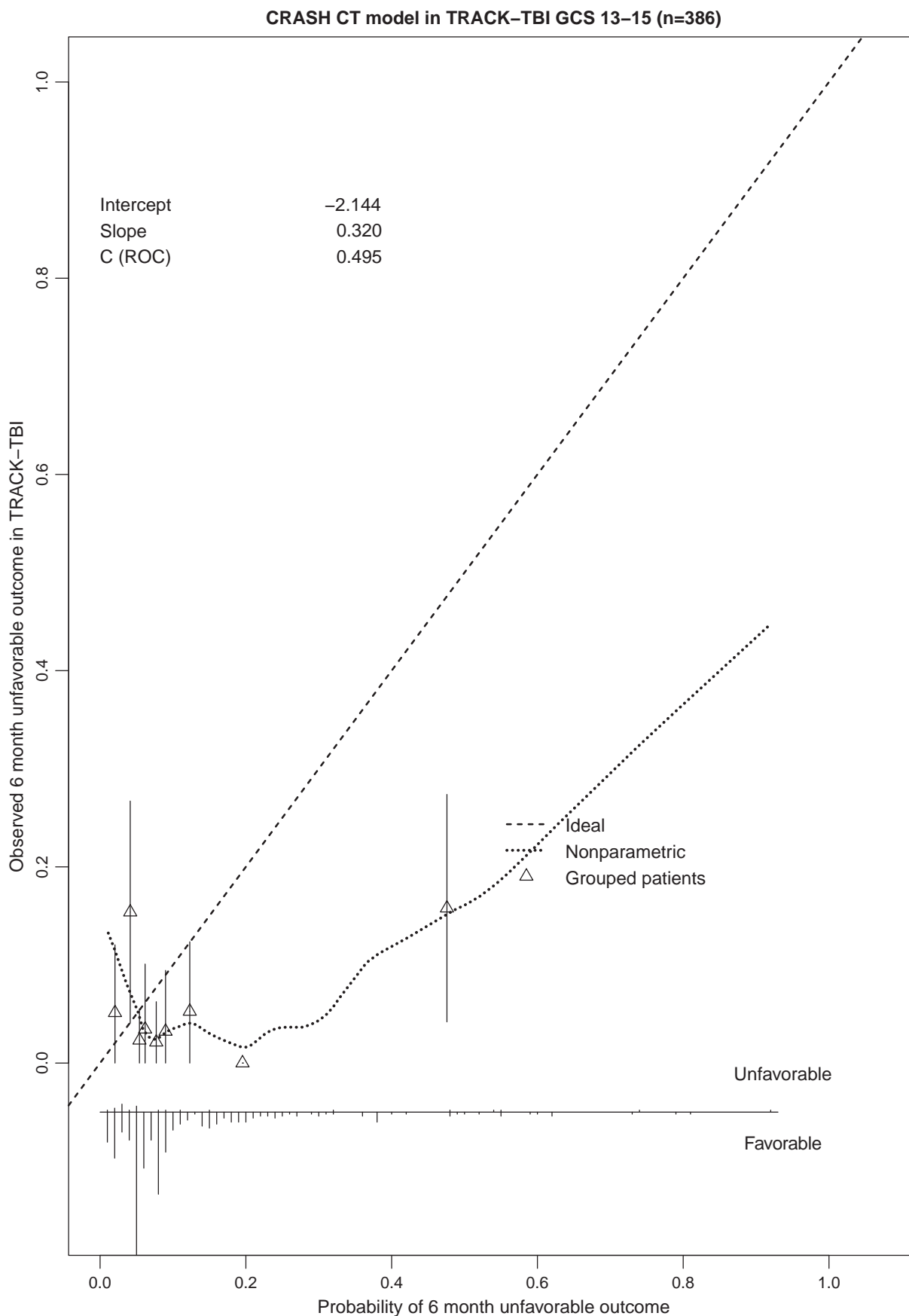
FIG. 2. Calibration plot CRASH computed tomography model. x-axis shows predicted probabilities by the model in quintiles of patients (triangles with horizontal lines as 95% confidence intervals); y-axis shows observed probabilities. Dotted diagonal represents perfect predictions. Spikes along the x-axis are numbers of patients with favorable and unfavorable observed outcomes. ROC, receiver operating characteristic.
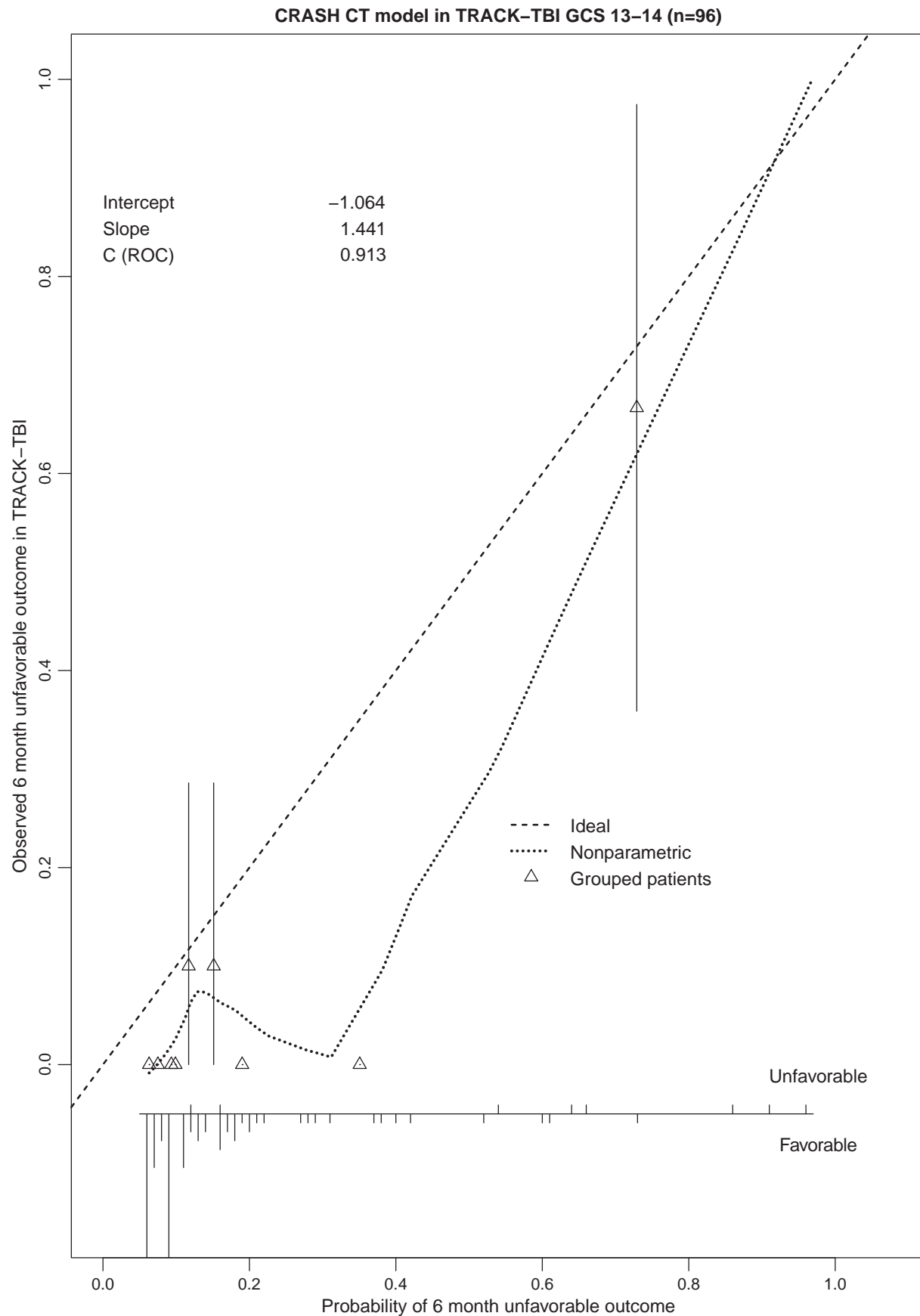
FIG. 3. Calibration plot CRASH computed tomography model (original population). x-axis shows predicted probabilities by the model in quintiles of patients (triangles with horizontal lines as 95% confidence intervals); y-axis shows observed probabilities. Dotted diagonal represents perfect predictions. Spikes along the x-axis are numbers of patients with favorable and unfavorable observed outcomes. ROC, receiver operating characteristic.

difference between the discriminative ability in the development data (AUROCs, 0.57–0.71) and in the validation data likely indicate that the Jacobs model is overfitted, but may also be attributed to true differences in prognostic relations.

The CRASH models discriminated equally poor in the total mTBI population, with AUROCs of 0.49–0.50. However, the CRASH models were not developed for patients with a GCS of 15, which was the majority of our sample. When patients with GCS 15 were excluded, the CRASH models discriminated well. In contrast to the Nijmegen models, the CRASH models were developed by testing 14 predictors in 3556 outcome events and were internally and externally validated in moderate and severe TBI.[26] It should be noted that the outcome predicted by the CRASH models was GOS < 4, whereas the Nijmegen model predicts GOS-E < 7. Possibly, it is easier to discriminate between patients above or below a cutoff in the middle of the GOS-E, compared with a cutoff at the higher end. This is supported by the finding that our ordinal multivariable models had AUROCs of 0.68–0.69, representing the discriminative ability over the complete GOS-E. When the models were refitted with CRASH outcome GOS < 4, the AUCs increased to 0.86. In all, the validation of these previously developed models supports the need for further research to develop valid prognostic models for mTBI patients.

Predictors of unfavorable outcome

Age, pre-existing psychiatric conditions, and lower education were the strongest predictors for both 3- and 6-month GOS-E in our data. Older age is a recognized predictor of poorer outcome in many diseases, including TBI, and our finding is consistent with the literature.[27] Pre-existing psychiatric conditions are less often studied, but also have been found to predict unfavorable outcome.[28] While speculative, it is possible that individuals with a pre-existing mental health condition may have less reserve to overcome the additional strain of an mTBI. Alternatively, symptoms that relate primarily to this comorbidity may falsely be attributed to the head injury.[29] More highly educated patients may have more-adaptive coping skills that allow them to return to their previous levels of functioning.[7]

Additional strong predictors of lower 6-month GOS-E were injury caused by assault, extracranial injury, and lower GCS. GCS is an indication of more-severe injury resulting in less favorable outcome. Violence as a cause of injury has been previously described as a predictor of fatigue after mTBI. The researchers suggested that post-traumatic stress might play a role in this relation.[28] Extracranial injury may result in disability independent of the head injury and has been described as a predictor of poor outcome before, especially in unselected TBI populations.[30]

It has been suggested that in moderate and severe TBI, outcome is determined by what ''the injury brings to the patient'' whereas in mTBI it is what ''the patient brings to the injury,'' and our data support this statement. Generally accepted prognostic models for moderate and severe TBI include, in addition to age, indicators of injury severity, such as GCS, pupillary reactivity, and CT parameters.[9,10,26] These predictors are less relevant in mTBI. Here, indicators of social background, history of psychiatric conditions, assault as cause of injury, and low education seem to be predictive of poorer outcome. However, the combination of pre-existing psychiatric conditions, low education, and assault as a cause of injury as predictors of 6-month outcome poses the question of whether persistent complaints are fully attributable to the TBI. Future studies that follow up with more-sensitive and -specific outcome measures in larger cohorts are required to answer this question. In this study, we neither aimed nor had enough patients to fully disentangle the mechanisms causing poor outcome. This would be essential to target treatment to patients at high risk for poor outcome and should be a main focus of future studies and large ongoing efforts such as CENTER-TBI and TRACK-TBI.

The predictors we combined in our multi-variable analysis had a moderate discriminative ability (AUROCs, 0.68''0.69). Emerging technologies that could improve prognostication in mTBI include proteomic biomarkers,[31–33] genetic factors,[34–36] and improved imaging biomarkers, including magnetic resonance imaging.[37] Additionally, prediction models for mTBI may require more-sensitive and -specific outcome measures beyond the GOS-E.

We recognize several limitations to our study. We included patients with GCS 13–15, which are classified in the category of mTBI. However, there were patients with one or two unreactive pupils, an AISh of 4 or 5, or a Marshall's CT classification of 5 or 6 (indicative of ''complicated'' mTBI with pathological head CT findings), all indicating quite severe injury. More than half of the patients reported previous head injury, which may be an overestimation given that it was self-reported without necessarily requiring hospital admission. Pre-existing psychiatric conditions proved to be one of the strongest predictors to poorer outcome. A goal of the TRACK-TBI Pilot Study was to evaluate the feasibility of implementing the TBI CDEs V1.0, which did not include a validated structured interview for preinjury psychiatric history. Even though we implemented the highest level of granularity for baseline data collection, we were unable to capture the specific types, durations, and formal diagnoses of pre-existing psychiatric conditions. In moving forward, establishing a standard set of tools and questionnaires to obtain this level of granularity will be helpful in evaluating the true associations among pre-existing mental health conditions and post-TBI outcome.

Conclusion

Reliable outcome prediction in mTBI is important for clinical practice. Identifying patients at increased risk of unfavorable outcome permits targeting closer observation and early intervention, which may reduce the psychological burden of injury on patients, as well as the related economic burden on society. Our study demonstrates that existing models for mTBI perform unsatisfactorily. We tested 21 variables in ordinal analysis of 386 patients, which is 1 in 18 and thus reasonable from a statistical perspective. Although we have found some strong predictors of poor outcome, such as age and history of psychiatric condition, given the sample size, we consider the results of our prognostic analysis as hypothesis generating. These predictors will need further validation in ongoing prospective, longitudinal studies, such as those that are part of the International TBI Research Initiative.[38,39]

Acknowledgments

Author Disclosure Statement

No competing financial interests exist.

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Measurement of the Glial Fibrillary Acidic Protein and Its Breakdown Products GFAP-BDP Biomarker for the Detection of Traumatic Brain Injury Compared to Computed Tomography and Magnetic Resonance Imaging

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Abstract

Glial fibrillary acidic protein and its breakdown products (GFAP-BDP) are brain-specific proteins released into serum as part of the pathophysiological response after traumatic brain injury (TBI). We performed a multi-center trial to validate and characterize the use of GFAP-BDP levels in the diagnosis of intracranial injury in a broad population of patients with a positive clinical screen for head injury. This multi-center, prospective, cohort study included patients 16–93 years of age presenting to three level 1 trauma centers with suspected TBI (loss of consciousness, post-trauma amnesia, and so on). Serum GFAP-BDP levels were drawn within 24 h and analyzed, in a blinded fashion, using sandwich enzyme-linked immunosorbent assay. The ability of GFAP-BDP to predict intracranial injury on admission computed tomography (CT) as well as delayed magnetic resonance imaging was analyzed by multiple regression and assessed by the area under the receiver operating characteristic curve (AUC). Utility of GFAP-BDP to predict injury and reduce unnecessary CT scans was assessed utilizing decision curve analysis. A total of 215 patients were included, of which 83% suffered mild TBI, 4% moderate, and 12% severe; mean age was 42.1 ± 18 years. Evidence of intracranial injury was present in 51% of the sample (median Rotterdam Score, 2; interquartile range, 2). GFAP-BDP demonstrated very good predictive ability (AUC = 0.87) and demonstrated significant discrimination of injury severity (odds ratio, 1.45; 95% confidence interval, 1.29–1.64). Use of GFAP-BDP yielded a net benefit above clinical screening alone and a net reduction in unnecessary scans by 12–30%. Used in conjunction with other clinical information, rapid measurement of GFAP-BDP is useful in establishing or excluding the diagnosis of radiographically apparent intracranial injury throughout the spectrum of TBI. As an adjunct to current screening practices, GFAP-BDP may help avoid unnecessary CT scans without sacrificing sensitivity (Registry: ClinicalTrials.gov Identifier: NCT01565551).

Key words: biomarkers; imaging; traumatic brain injury

Introduction

Clinical care and research in traumatic brain injury (TBI) rely on classification systems, such as the Glasgow Coma Scale (GCS), that are not adequately calibrated for injury assessment across mild and moderate TBI.[1] Radiographic evaluation is central to the initial stratification of injury severity and to monitor for acute changes; however, its use is limited by cost and perceived risk of ionizing radiation.

Simpler, sensitive, and specific tests for identifying and stratifying TBI would provide more rapid and tailored diagnosis of TBI

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while minimizing the time, risk, and cost associated with current standards. To this end, there has been increasing investigation into serum proteins as biomarkers of TBI; however, none have yet been validated for routine use. Potential biomarkers under investigation include glial protein S-100 beta (S100B), neuron-specific enolase (NSE), myelin basic protein, ubiquitin c-terminal hydrolase, and glial fibrillary acid protein (GFAP).[2,3] GFAP, initially investigated in the 1970s, has emerged as a promising biomarker candidate to improve diagnosis, triage, and targeted treatment of TBI patients.[4] GFAP is an intermediate filament protein component of the astrocyte cytoskeleton expressed almost exclusively in the central nervous system (CNS). While insoluble in intact astrocytes, overactivation of calpain after initial injury and gliolysis produce soluble GFAP polymers (or breakdown products) that are released into interstitial fluid.[5] These GFAP breakdown products (GFAP-BDP) can be measured in serum in association with a number of CNS disorders, including TBI.[1,2] Previous studies have correlated elevated GFAP-BDP with the presence of clinical and radiographic injury as well as worse outcome and need for neurosurgical intervention.[2,3] To date, previous work has focused primarily on the severe TBI population or compared TBI patients against either uninjured patients or those not meeting clinical criteria for head injury. Our previous study was one of the first to prospectively assess GFAP-BDP with regard to presence and severity of radiographic injury on computed tomography (CT) across the entire spectrum of disease after TBI.[4,6]

The aim of this study was to evaluate and validate the utility of GFAP-BDP for the diagnosis of intracranial injury in patients with a positive clinical screen for head injury across the spectrum of TBI typically presenting to a level 1 trauma center. We expand on our previous analysis of the utility of GFAP-BDP to identify TBI, including injury evaluation by MRI, cut-off values for GFAP-BDP specifically in the mild and moderate TBI groups, and analysis of the potential reduction of CT scans by utilizing the biomarker for injury detection.[6]

Methods

Study population

Recruitment of subjects was part of the TRACK-TBI (Transforming Research and Clinical Knowledge in Traumatic Brain Injury) Pilot Study, a National Institute of Neurological Disorders and Stroke–funded, multi-center, prospective collaboration among three U.S. level 1 trauma centers enrolling acute TBI patients (University of Pittsburgh Medical Center [UPMC]; University Medical Center Brackenridge [UMCB]; and University of California, San Francisco [UCSF]) and one rehabilitation center (Mount Sinai Rehabilitation Center) enrolling late-presenting TBI patients to develop, test, and refine TBI common data elements (TBI-CDEs) for research across four major domains: demographics, neuroimaging, biomarkers, and outcome measures.[7] The TBI population under investigation spanned the entire injury spectrum, from severe to mild. Both patients with negative imaging and those discharged from the emergency department (ED) are also included in the total population. Institutional review boards of participating centers approved all study protocols. All participants or their legal authorized representatives gave written informed consent. At follow-up, participants previously consented by legal authorized representative, if neurologically improved to be cognizant, were consented for continuation in the study.

To be eligible for this analysis, patients must have presented to an ED within 24 h of their injury and had a positive clinical screen for acute TBI necessitating a noncontrast head CT according to American College of Emergency Physicians/Centers for Disease

Control and Prevention (ACEP/CDC) evidence-based joint practice guidelines.[8] These guidelines represent an amalgam of the Canadian CT Head Rule and the New Orleans Criteria (Haydel, Indications for computed tomography in patients with minor head injury; Stiell, The Canadian CT Head Rule for patients with minor head injury). GCS score was assessed by a neurosurgeon at admission and was reconfirmed by study personnel at the time of biomarker collection. TBI severity was broadly defined by GCS, with mild between 13 and 15, moderate between 9 and 12, and severe between 3 and 8. Patients were excluded if they were younger than 16 or greater than 95 years of age, suffered penetrating head injury, or had a premorbid neurologic condition.

Sample collection and measurement of glial fibrillary acidic protein and its breakdown products

Data from the three level 1 trauma centers were used for this analysis. Serum samples were collected within 24 h of injury and were dated and time stamped to compare with time of injury. The TBI-CDE Biospecimens and Biomarkers Working Group Guidelines for sample preparation were followed.[9] Samples were centrifuged and serum aliquots stored at −80°C for future batch processing. UPMC and UMCB batch-shipped samples, overnight on dry ice, to UCSF. All deidentified samples were then stored with a unique study number specific to site and subject. A central database was maintained by the coordinating center (UCSF) with each site entering site-specific data for final statistical reporting. Blinded sample analysis occurred in a single laboratory (Banyan Biomarkers, Alachua, FL) using a sandwich enzyme-linked immunosorbent assay (ELISA) to GFAP-BDP. The GFAP ELISA utilized a proprietary mouse monoclonal antibody for solid-phase immobilization, and a proprietary polyclonal rabbit antibody for detection.[10,11] Testing procedure and detection of GFAP was carried out as previously described.[6] Both whole GFAP molecules as well as GFAP-BDPs are detected by the assay, potentially resulting in a more complete measure of overall GFAP released into circulation. All samples were analyzed in duplicate concomitantly with calibrators prepared in compatible matrix, as described previously.[6] From high concentration to low, the previously reported intraassay coefficient of variance for the ELISA is 4.3–7.8% and the interassay coefficient of variance is 7.8–14.3%. The estimated limit of detection for GFAP is ∼0.01 ng/mL.[11]

Evaluation of endpoints

All patients underwent CT imaging of the brain at the time of initial presentation to the ED. Patients were offered a follow-up, out-patient MRI upon enrollment in the TRACK-TBI study. The MRI was on a voluntary, opt-in basis to be performed 1–2 weeks postinjury. Radiographic images were deidentified, uploaded to a central imaging database, and reviewed by a blinded central reader. Imaging features were extracted and entered into the TRACK-TBI database. Each patient's head CT and magnetic resonance image (MRI) were characterized using the recommendations of the TBI-CDE Neuroimaging Working Group regarding specific radiologic features, data definitions needed to characterize injuries, and best practices needed to optimize and harmonize imaging data acquisition for TBI research during data collection.[12,13] Specifically, the presence of cisternal effacement, mid-line shift, epidural hematoma, subarachnoid hemorrhage, and intraventricular hemorrhage were recorded to determine the Rotterdam score for all scans (assessment of TBI severity based on noncontrast head CT). The presence of any intracranial abnormalities on MRI was considered a positive scan. Imaging studies were performed at the discretion of each study site using their standard equipment and protocols.

The primary endpoint for analysis was intracranial injury, as identified on CT scan at time of presentation. Secondary endpoints included severity of intracranial injury, as measured by the

Rotterdam score, and presence of intracranial injury, as identified by delayed MRI.

Statistical analysis

Continuous demographic characteristics were assessed for normality using the Kolmogorov-Smirnov's test; normally distributed data were analyzed by *t*-test, whereas the remainders were compared using the Wilcoxon's rank-sum test. Categorical data were analyzed by Pearson's chi-squared or Fisher's exact test. Differences between groups in multi-level ordinal measurements (i.e., Rotterdam score, GCS, and Glasgow Outcome Scale) were tested using Kruskal-Wallis' test. Univariable regression analysis was performed to assess the association between GFAP-BDP level and radiographic presence of intracranial injury. Multi-variate regression models were later built to evaluate the predictive capabilities GFAP-BDP after adjustment for known factors associated with severity of intracranial injury (age, pupillary reactivity, GCS, and Injury Severity Score [ISS]). The ability of GFAP-BDP to predict severity of intracranial injury was assessed using ordered logistic regression modeling.

The ability of GFAP-BDP to predict the presence of intracranial injury was analyzed apropos of accuracy, discrimination, calibration, and clinical utility. Discrimination was assessed using the area under the receiver operating characteristic (ROC) curve (AUC). Using current statistical consensus, AUCs of 0.8–0.9 are considered very good, 0.7–0.8 as adequate, and below 0.7 as poor. Calibration was tested with the Hosmer-Lemeshow's goodness-of-fit test. Cut-off values for GFAP-BDP were assessed both for the highest accuracy and for the highest specificity, specifically in the mild to moderate injury groups. Values were determined utilizing ROC curves and AUC and Brier scores were calculated. Clinical utility was evaluated by decision curve analysis.[14] Statistical significance was set at $p < 0.05$. All data were analyzed using STATA statistical software (12; StataCorp LP, College Station, TX).

Results

Baseline demographics

A total of 215 patients were available for analysis. Demographic characteristics are shown in Table 1. Mean age was 42 ± 18 years, with a minimum of 16 and maximum of 93 years. Approximately 73% of patients were male. Median GCS for the entire sample was 15 (interquartile range [IQR], 1), with mild TBI (GCS, 13–15) constituting 83% (GCS,13–15), moderate 4% (GCS, 9–12), and severe 13% (GCS, 3–8). Seventy percent of patients had a documented loss of consciousness (LOC), whereas 38% had documented post-traumatic amnesia (PTA). Median Injury Severity Score (ISS) was 10 (IQR, 17), with 36% suffering significant polytrauma (ISS, ≥16). Mean GFAP-BDP was 1.59 ± 2.98 ng/mL, and minimum and maximum levels detected were 0.02 and 20.1 ng/mL, respectively. Pair-wise correlation between CT and MRI was 0.33 ($p = 0.0096$). There was no significant correlation between MRI and Rotterdam score.

Glial fibrillary acidic protein and its breakdown products and computed tomography outcomes

Fifty-one percent ($n = 110$) of patients presenting with positive clinical screen for TBI had intracranial pathology demonstrated on admission CT. Median Rotterdam score of this cohort was 3 (IQR, 1). Serum level of GFAP-BDP was significantly higher in those with CT-positive intracranial injury, compared to those without (2.86 ± 3.74 vs. 0.26 ± 0.41 ng/mL, respectively; $p < 0.001$). Figure 1 presents a box plot of GFAP-BDP values for the two patient cohorts. Univariable analysis demonstrated elevated GFAP-BDP level and conferred significant risk of intracranial injury on initial CT (odds ratio [OR], 8.9; 95% confidence interval [CI], 2.3–2.5; $p < 0.001$), as also demonstrated in our previous study.[6] Further, elevated GFAP-BDP remained a significant predictor after adjustment for known predictors of intracranial injury severity and functional outcome (i.e., age, pupillary activity, GCS, and ISS; OR, 5.5; 95% CI, 2.00–14.9; $p < 0.001$).

Figure 2 shows GFAP-BDP levels in relation to radiographic injury severity classification according to Rotterdam score. Level of GFAP-BDP differed significantly as a function of Rotterdam score ($p < 0.001$). Ordinal regression analysis revealed that elevated GFAP-BDP level significantly predicted worse Rotterdam score, both independently (OR, 1.20; 95% CI 1.1–1.3) as well as after adjustment for age, GCS, and ISS (OR, 1.17 95% CI, 1.1–1.3; $p < 0.001$).

GFAP-BDP level was the most accurate predictor of the presence or absence of intracranial injury detected by radiographic imaging (accuracy, 81%), as compared with accepted clinical predictors of intracranial injury (age, 65%; GCS, 62%; LOC and/or

TABLE 1. BASELINE DEMOGRAPHIC CHARACTERISTICS AT TIME OF ADMISSION BY PRESENCE OF INTRACRANIAL INJURY ON CT

Baseline characteristics	All (n = 215)	CT negative (n = 105)	CT positive (n = 110)	p value
Age, mean ± SD (years)	42 ± 18	37 ± 16	47 ± 18	<0.01
Sex, % male	73 (156)	69 (72)	76 (84)	0.22
GCS, median (IQR)	15 (1)	15 (0)	15 (4)	<0.01
Mild, % 13–15	83 (179)	97 (102)	70 (77)	
Moderate, % 9–12	4 (9)	2 (2)	6 (7)	
Severe, % 3–8	13 (27)	1 (1)	24 (26)	
Pupillary reactivity, %				<0.01
Both	94 (202)	100 (105)	88 (97)	
Anisocoria	2 (4)	—	4 (4)	
Unreactive	4 (9)	—	8 (9)	
ISS, median (IQR)	10 (17)	0 (4)	17 (12)	<0.01
Polytrauma, % ISS ≥16 (n)	36 (78)	5 (5)	66 (73)	<0.01
Rotterdam score, median (IQR)		—	3 (1)	
GFAP-BDP, mean ± SD (ng/mL)	1.59 ± 2.98	0.26 ± 0.41	2.86 ± 3.74	<0.01

CT, computed tomography; GCS, Glasgow Coma Score; ISS, Injury Severity Score; SD, standard deviation; IQR, interquartile range; GFAP-BDP, glial fibrillary acidic protein and its breakdown products.
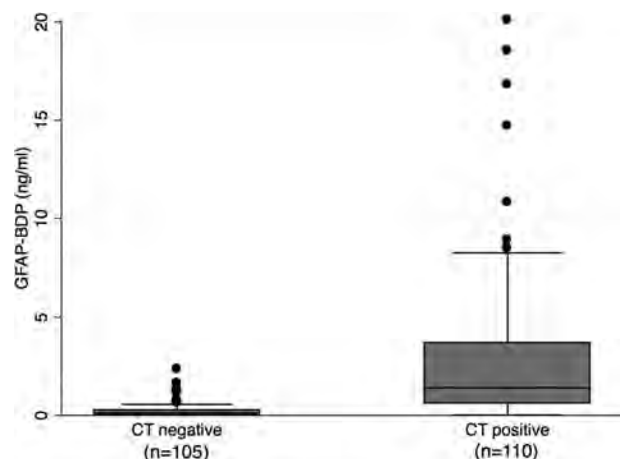
FIG. 1. Box plots showing median levels of GFAP-BDP measured on admission in two groups of patients. Boxes show interquartile ranges, and I bars represent highest and lowest values. CT, computed tomography; GFAP-BDP, glial fibrillary acidic protein and its breakdown products.

PTA, 54%; pupillary status, 52%). In our sample, accuracy of GFAP-BDP for injury prediction was superior to the ACEP/CDC recommended criteria for neuroimaging in TBI (81% vs. 65%, respectively).[8] Discriminatory analysis of GFAP-BDP resulted in an AUC of 0.88 (95% CI, 0.83–0.93), indicating very good discriminatory ability. Level of GFAP-BDP retained its discriminatory value after adjustment for age, pupillary exam, GCS, and ISS (AUC, 0.96; 95% CI, 0.7–0.91; Fig. 3). Calibration analysis did not show systematic error across risk deciles ($p = 0.15$). Calculation of a cut-off value to maximize accuracy in the mild and moderate injury range specifically yielded a GFAP-BDP level of 0.6 ng/mL, with a sensitivity of 67%, a specificity of 89%, and a Brier score of 0.21. A cut-off value to maximize specificity was calculated at a GFAP-BDP concentration of 1.66 ng/mL, resulting in a sensitivity of 45%, specificity of 99%, and a Brier score of 0.29.
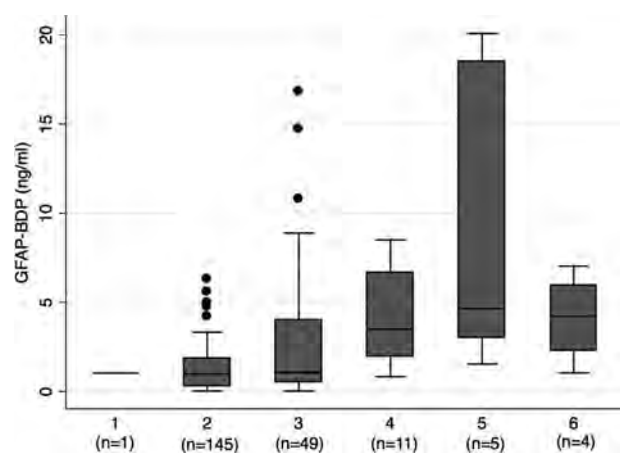
FIG. 2. Box plots showing median levels of GFAP-BDP measured on admission among patients in each of the Rotterdam classifications of injury on CT. Boxes show interquartile ranges, and I bars represent highest and lowest values. Overall, GFAP-BDP was significantly different across each level of Rotterdam score ($p \leq 0.001$). CT, computed tomography; GFAP-BDP, glial fibrillary acidic protein and its breakdown products.
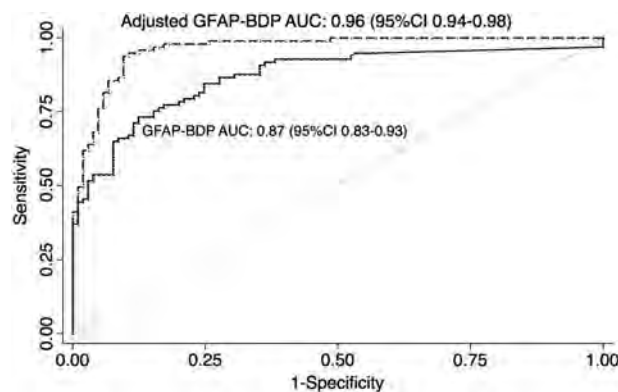
FIG. 3. Receiver-operating-characteristic curves for various cut-off levels of GFAP-BDP in differentiating presence or absence of intracranial injury on CT. Curves for GFAP-BDP alone and after adjustment for known predictors of injury and severity (age, GCS, pupillary reactivity, and ISS). AUC, area under the receiver operating characteristic curve; CI, confidence interval; CT, computed tomography; GCS, Glasgow Coma Scale; GFAP-BDP, glial fibrillary acidic protein and its breakdown products; ISS, Injury Severity Scale.

Clinical utility of GFAP-BDP was evaluated through decision curve analysis as an extension of currently established practice guidelines.[15] Decision curves are displayed in Figure 4. Use of GFAP-BDP displayed superior net benefit, as compared to scanning all patients with a positive clinical screen for head injury beginning at a threshold probability (i.e., perceived risk of injury) of approximately 20% or higher. This correlated to a net reduction of 12 CT scans per 100 patients without missing a single injury (12% reduction in unnecessary imaging). Reduction of unnecessary scans increased to 18% when applied to patients with a perceived risk of injury of 25% and by more than 30% if the risk of injury was equivalent to the prevalence of injury in this sample (CT-positive after clinical screen, ~51%).

Glial fibrillary acidic protein and its breakdown products and magnetic resonance imaging outcomes

Sixty patients underwent MRI in the subacute injury phase; of these, 35% ($n = 21$) had positive scans (see Table 2). Of note, MRI revealed injuries in 13 patients who had had negative CT imaging on initial evaluation. Further, 4 patients with positive CT scans had negative follow-up findings on MRI. There was no significant difference between MRI-positive and -negative patients in age, gender, pupillary status, GCS, ISS, or functional outcome (Glasgow Outcome Scale Extended at 6 and 12 months). Admission GFAP-BDP values were significantly higher in MRI-positive patients (1.31 ± 1.8 vs. 0.28 ± 0.57 ng/mL, respectively; $p = 0.001$). In univariable analysis, GFAP-BDPs significantly predicted the presence of intracranial pathology, as observed on MRI (OR, 2.7; 95% CI, 1.2–5.7). GFAP-BDP remained an independent predictor of injury on MRI after multivariate analysis, adjusting for age, pupillary status, GCS, and ISS (OR, 3.8; 95% CI, 1.3–11.3). Post-hoc, subgroup analysis performed on CT-negative, MRI-positive patients, in comparison with the remainder of the CT-negative cohort (35 patients), did not demonstrate significant differences in age, GCS, ISS, or GFAP-BDP levels.

Analysis of GFAP-BDP for the prediction of injury on MRI demonstrated an accuracy of 72%, adequate discrimination of 0.70
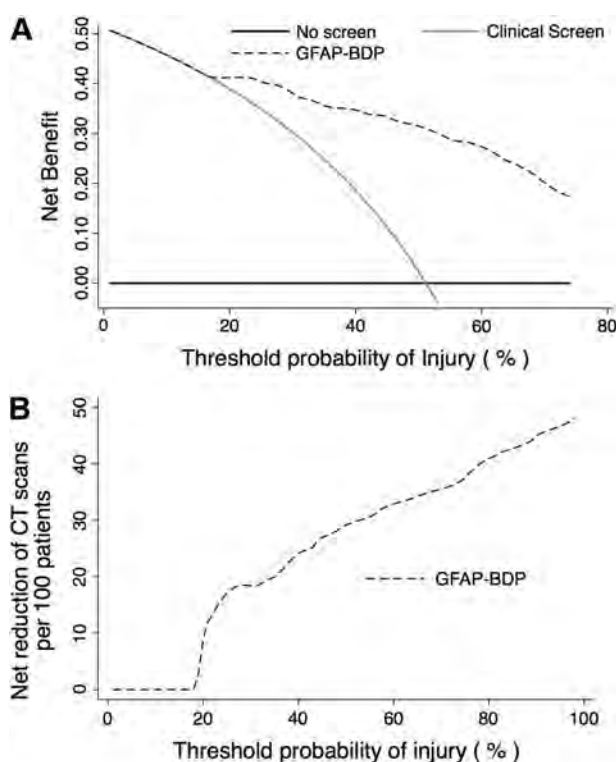
FIG. 4. (**A**) Decision curve analysis of the net benefit of GFAP-BDP to predict injury compared to current clinical screening method or scanning all patients regardless of screening across various probabilities of injury. (**B**) Decision curve analysis of the reduction of unnecessary CT scans per 100 patients using GFAP-BDP as an adjunct to predict injury compared to current clinical screening methods across various probabilities of injury. CT, computed tomography; GFAP-BDP, glial fibrillary acidic protein and its breakdown products.

(AUC; 95% CI, 0.55–0.85), and adequate calibration ($p=0.41$). Decision curve analysis demonstrated that GFAP-BDP contributes a net benefit above an injury-risk threshold of 25%, with a 13% reduction in unnecessary scans. Utilization of the cut-off value of 0.6 ng/mL in the mild-to-moderate range of injury was calculated to have a net benefit at an injury threshold of 24% and an overall net reduction in CT scans of 30 per 100 patients in this group.

TABLE 2. BASELINE DEMOGRAPHIC CHARACTERISTICS AT TIME OF ADMISSION BY PRESENCE OF INTRACRANIAL INJURY ON MRI

Baseline characteristics	MRI negative (n=39)	MRI positive (n=21)	p value
Age, mean ± SD (years)	39 ± 17	42 ± 15	0.32
Sex, % male	64 (25)	76 (16)	0.33
GCS, median (IQR)	15 (0)	15 (0)	0.68
ISS, median (IQR)	0 (0)	0 (10)	0.12
GFAP-BDP, mean ± SD (ng/mL)	0.28 ± 0.57	1.31 ± 1.77	<0.01

MRI, magnetic resonance imaging; GCS, Glasgow Coma Score; ISS, Injury Severity Score; SD, standard deviation; IQR, interquartile range; GFAP-BDP, glial fibrillary acidic protein and its breakdown products.

Discussion

This multi-center, prospective study demonstrates that serum measurement of GFAP-BDP as a biomarker possesses the necessary characteristics (accuracy, discrimination, calibration, and clinical utility) for improved prediction of radiographically evident injury across the spectrum of TBI. Additionally, GFAP-BDP levels were able to discriminate severity of intracranial injury independent of other classic injury predictors. GFAP-BDP also accurately predicted persistence of intracranial injury on imaging performed in the subacute period, again independent of other markers of injury risk. These data expand upon our previous study demonstrating a correlation between injuries observed on CT scan and elevated levels of GFAP-BDP.[6] Taken together, these results indicate that GFAP-BDP is a viable early indicator of intracranial injury and represents a useful adjunct to current diagnostic methods for TBI.

Numerous serum biomarker candidates for the diagnosis of TBI have come under intense scrutiny; however, none to this point have demonstrated sufficient utility to justify routine clinical use. Studies have reported a consistent correlation between elevated serum levels of S-100B and GCS, radiographic findings, and outcome.[16] Despite its sensitivity, S-100B has been shown to be elevated in trauma patients without head injury, as well as after hemorrhagic shock and in normal pediatric patients.[16] This lack of specificity limits its possible diagnostic practicality. Similarly, NSE, although rapidly elevated post-TBI, is also found in states of hemolysis.[17] GFAP-BDP is a product of astrocyte cytoskeleton degradation by calpain protease activation and therefore considered specific to the CNS. This has already been corroborated by a number of studies evaluating levels after TBI, compared to noninjured controls, as well as those suffering only traumatic extracranial injuries.[11,18] This study further supports the specificity of GFAP-BDP to detect radiographically evident injury given that predictive ability was evaluated among patients with similar clinical scenarios and presenting neurological exams. Against this clinically relevant sample, GFAP-BDP remained a sensitive and specific predictor of injury even after adjustment for the presence of polytrauma (i.e., ISS).

Previous evaluations of GFAP-BDP, largely focusing on severe TBI, have demonstrated a correlation between elevated marker levels and injury severity, number of lesions, and mortality.[19] More recently, Papa and colleagues specifically studied GFAP-BDP within the mild-to-moderate TBI population and found that GFAP-BDP adequately predicted presence of injury, severity of injury, and need for neurosurgical intervention.[11] The current study evaluates GFAP-BDP across the entire spectrum of TBI, in the context of all patients who screen positive for intracranial injury using established guidelines. Alone, GFAP-BDP demonstrated the highest accuracy among predictors and very good discrimination (AUC, 0.88). Importantly, despite varied injury states and severity, calibration did not demonstrate systematic errors, further supporting the use of GFAP-BDP across severity cohorts. Importantly, GFAP-BDP also independently predicted the degree of radiographic injury throughout the spectrum of presenting neurological exams. This correlation supports the idea that GFAP release, breakdown, and translocation to serum mirrors radiographic evidence of parenchymal injury and disruption of the blood–brain barrier.

Pressure to deliver cost-effective care and concern over the potential effects of unnecessary ionizing radiation have prompted more judicious use of CT imaging for the evaluation of head injury. Despite the implementation of the Canadian CT Head Rule and/or New Orleans Criteria to stratify patients, approximately 60–90% of

patients imaged for head injury will have a negative CT.[20] Biomarkers, ideally, could act as adjuncts to these validated approaches, to better and more cost-efficiently classify at-risk patients. To assess clinical utility in this context, we analyzed GFAP-BDP utilizing decision curve analyses to determine the probability of injury above which GFAP-BDP benefits diagnosis without increasing unnecessary scans. This study found that use of GFAP-BDP has a superior net benefit from a threshold probability of injury of 20% and greater. This suggests that measuring serum GFAP-BDP, in conjunction with current practice guidelines, would lead to a 12% reduction in unnecessary imaging at this relatively low-risk threshold for injury (common probability thresholds for cancer and cardiac screening are 10–20%). Specifically in the mild to moderate groups, where there is the most potential benefit from a reduction in CT scans, we calculated that, at a concentration of 0.6 ng/mL, there is a net benefit at an injury probability threshold of 24% with a potential reduction in scans of 30 per 100 patients. When used as an adjunct to ACEP Guidelines, GFAP-BDP would reduce unnecessary CT scans by greater than 20% at a risk threshold of 25%, and by more than 30% in a population with a prevalence of injury similar to our sample (∼51%).[8] Currently only 6–10% of patients with GCS 13–15 have lesions detected on CT scan, and only 0.4–1% of these require neurosurgical intervention, indicating that many patients may not need imaging if other reliable and accurate options for injury detection are available.[21] With approximately 1.5 million patients diagnosed as sustaining a mild TBI, estimating 80% receive a CT scan, and an average cost of $216 per CT scan, a reduction in scans of 30% could yield a potential savings of $77.8 million dollars per year in this population.[22,23]

There are several limitations to our study. GFAP-BDP was only measured at initial presentation and thus levels were unable to be trended to evaluate whether decreasing GFAP-BDP correlates with injury resolution or to track the trend in concentration over time. This precluded analysis of changes in concentration of GFAP-BDP over time as compared to evolution of injury on imaging. Our analysis included only those patients who received a head CT as part of enrollment in the TRACK-TBI study, and we therefore had a relatively high number of mild TBI patients with positive findings on CT scan. This may have excluded the less severely injured patients from GFAP-BDP measurement. Additionally, our analysis was limited to the clinical indicators of injury as defined by the TRACK-TBI study, and we were unable to compare GFAP-BDP against the numerous indicators of intracranial injury that may otherwise be used. We also were unable to include cost data on serum analysis for GFAP-BDP concentrations given that the data are publicly not available and remain confidential owing to the fact that the test is not yet U.S. Food and Drug Administration approved for clinical use. Therefore, we were unable to provide further analysis as to potential cost savings compared to CT scans. This is the first study, to our knowledge, to evaluate the performance of GFAP-BDP against the Rotterdam score and against positive findings on MRI. However, MRI data were collected on an opt-in basis at up to 2 weeks postinjury, potentially biasing this cohort to include patients with more-severe or persistent symptoms. This may help to account for the lower discriminatory ability of GFAP-BDP among MRI patients; nonetheless, GFAP-BDP remained a significant predictor after adjustment.

This analysis demonstrates that GFAP-BDP can reliably detect the presence of injury on radiographic imaging as well as predict injury severity across the spectrum of TBI. Early measurement of GFAP-BDP can contribute to more-accurate diagnosis and triage of

TBI patients, decreasing the number of unnecessary CT scans and allowing more tailored management of the brain injury.

Author Disclosure Statement

No competing financial interests exist. No conflicts of interest.

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